Vermont State Agency Application: VHCURES Standard Comprehensive Research Data Set

VERMONT
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APPLICATION INSTRUCTIONS

Introduction

The Vermont Health Care Uniform Reporting and Evaluation System (VHCURES)

The Vermont legislature authorized the collection of eligibility and claims data for Vermont residents to enable the Green Mountain Care Board (GMCB) to carry out its statutory duties that include determining the capacity and distribution of existing resources; identifying health care needs and informing health care policy; evaluating the effectiveness of intervention programs on improving patient outcomes; comparing costs between various treatment settings and approaches; providing information to consumers and purchasers of health care; and improving the quality and affordability of patient health care and health care coverage. (18 V.S.A. § 9410)

The GMCB is required to make the VHCURES data set available as a resource for individuals and entities to continuously review health care utilization, expenditures, and performance in Vermont to the extent permitted by the Health Information Portability and Accountability Act (HIPAA) and other pertinent state and federal laws.

The claims and eligibility data available under a data use agreement can be broadly grouped into three lines of business including commercial, Medicaid, and Medicare. The GMCB has independent discretion to make decisions regarding the use and disclosure of commercial insurer data. The Department of Vermont Health Access (DVHA) and the GMCB share discretion with respect to the Medicaid data subset. DVHA must approve the use and disclosure of Medicaid data and must sign the Data Use Agreement (DUA) for authorized users of the Medicaid data subset. Per an agreement with the federal Centers for Medicare and Medicaid Services (CMS), the Medicare data subset is available only to Vermont State Agencies and entities performing research that is directed and partially funded by the State of Vermont. Under a DUA between GMCB and CMS, GMCB has independent discretion to make decisions regarding the use and disclosure of the Medicare data subset by Vermont state agencies.

Vermont state agencies may apply for a standard comprehensive research data set that includes all unrestricted and restricted data elements for broad use internally and by state contractors. Non-state entities may apply for a DUA for a limited use health care claims research data set using a different application form. This type of data set excludes the Medicare data subset and is tailored to specific research purposes as approved by GMCB and DVHA if the Medicaid data subset is requested. Applicants who are non-state entities must justify requests for individual restricted data elements and explain how the requested restricted data elements are applicable to the intended research purpose.

Data Governance Council

The GMCB chartered the Data Governance Council (DGC) to oversee the stewardship of VHCURES including the development and revision of principles and policies to guide decisions on data use and disclosure. The DCG supports the GMCB decision-making process for applications requesting use and disclosure of VHCURES data sets by state agencies as addressed in this application form.

Application Review Process

This application is required of all state agencies requesting a DUA for the VHCURES standard comprehensive research data set with the option of including the commercial, Medicaid, and Medicare subsets included in the data set to support a broad spectrum of uses.

GMCB staff must deem this application complete before initiating the full review process. **This includes submission of all required and applicable optional attachments as listed in the Application Checklist in this application.** Applicants must include a full list of individuals who will have access to the data set upon the effective date of the DUA with this application. Applicants must file Individual User Affidavits (IUA) signed by the Authorized User (AU) or Principal Investigator (PI) for all data users listed on this application. AUs or PIs must ensure that IUAs are filed with GMCB for future data users prior to their access to the data set or risk forfeiture of the DUA and the data set.

After an application is deemed complete, GMCB will start the application review process that may include a public discussion of the application by the DGC. The GMCB has the discretion to approve or disapprove applications for a DUA. All requests for the Medicaid data subset must also be approved by the Department of Vermont Health Access (DVHA). The GMCB will provide DVHA with a copy of the complete application, following a review of the application by the GMCB.

The Agency of Administration (AOA) under "Procurement and Contracting Procedures" of Bulletin 3.5 is required to review and approve the DUA after the GMCB and DVHA, if applicable, have approved the application for a DUA. Applicants may also be required to obtain approval of the AHS Institutional Review Board (IRB) Committee. (See http://humanservices.vermont.gov/boards-committees/irb)

Pertaining to DUAs issued to Vermont state agencies, GMCB must review and approve requests by Vermont state agencies to re-disclose data including custom extracts to state contractors, subcontractors, or other entities external to the state agency for specified research and studies funded under Vermont state contracts and grants. Vermont state agencies must file project review forms (PRF) with the GMCB prior to re-disclosing the data set or any extracts generated from the data set. This ensures continued compliance with provisions of state and federal laws and regulations.

Final Steps in the Application Process

If approved by AOA, the GMCB and the applicant jointly enter into a DUA that is signed by the Authorized User, Principal Investigator, GMCB, and DVHA if the Medicaid data subset is included. Prior to receiving the data set approved under the DUA, all individuals accessing and using the data on behalf of the Authorized User must sign IUAs attesting to understanding the appropriate use and disclosure of the data set and agree to comply with the requirements. If GMCB declines an application, a written statement identifying the specific basis for denial of the application will be provided to the applicant. The applicant may resubmit or supplement the application to address GMCB's concerns including those of DVHA if Medicaid data are being requested. An adverse decision regarding an application may be appealed to the GMCB.

General Instructions

Applicants must complete all required sections of the application and submit an electronic copy of the completed application, including all attachments, to Roger.Tubby@vermont.gov. Incomplete applications will not be reviewed until the applicant has provided all required information. An application checklist is provided to help ensure that your application is complete. For questions about the application process, Roger.Tubby@vermont.gov or (802) 272-5599.

Definitions

Agent: Means any individual or entity (e.g., a contractor, subcontractor, grantee, or subgrantee) acting on behalf of the Authorized User and subject to the Authorized User's control or accessing the Data Set on behalf of the Authorized User.

Authorized User: The Authorized User (AU) is typically an organization or agency. The AU signatory to the Application and the DUA must have the authority to sign legally binding agreements on behalf of the organization or institution.

***Custom Extract*:** A custom extract includes the minimum necessary data to support the research purpose. A custom extract is a data subset or table generated from the standard comprehensive research data set with commercial, Medicaid, and Medicare data.

This process ensures continued compliance with the requirements of the DUA and particularly supports the concept of using the minimum necessary data to support the approved research purpose. For example, if a Vermont state agency hires a contractor to analyze VHCURES data for a study of pediatric asthma in the Medicaid population, the GMCB may approve use of a custom extract that includes Medicaid paid claims data for enrollees under the age of 19 only.

Data Custodian: The data custodian is responsible for the establishment and maintenance of physical and technical safeguards to prevent unauthorized access to and use of the data set. Agencies may designate multiple data custodians for different departments and programs. The data custodian(s) typically coordinate the receipt of the approved data set from GMCB's data consolidation vendor. The principal investigator may also be the data custodian. State contractors or other agents approved by the GMCB through a Project Review to receive the data set or custom extracts must identify and file contact information for their data custodian(s) with the GMCB.

Institutional Review Board (IRB): An institutional review board (IRB), also known as an independent ethics committee (IEC), ethical review board (ERB), or research ethics board (REB), is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans.

Principal Investigator (PI): The Principal Investigator means the individual designated by the Authorized User to be responsible for ensuring compliance with all the restrictions, limitations, and conditions of use and disclosure specified in the DUA. The Principal Investigator may delegate technical responsibility to other personnel for the establishment and maintenance of security arrangements to prevent unauthorized access to and use of the data.

Project Review: Any Vermont state agency with a DUA intending to re-disclose the VHCURES data set or any custom extracts of the data set to external agents to perform state-directed and funded research must file a Project Review Form (PRF) with the GMCB for review and approval prior to the re-disclosure.

After the GMCB has reviewed a Project Review Form (CPRF) and approved re-disclosure of data to an external agent, the Vermont state agency holding the DUA may generate custom data extracts for the contractor or other approved entities. As needed, the GMCB may request its data consolidation vendor to generate custom data extracts for the contractor or allow the contractor or other approved entities to access the secured data enclave hosted by the vendor. Use of services provided by the GMCB's data consolidation vendor may require payment of a fee to the vendor. This will be determined by GMCB a case-by-case basis after discussions with the state agency holding the DUA.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

State Entity: Vermont State agencies, contractors, or external agents performing work for the State of Vermont.

Application Checklist (For use by the applicant. Applicants must include all required attachments and applicable optional attachments)

Completed Application

☐ **Section 1:** Research Summary

☐ **Section 2:** Data Management Plan

☐ **Section 3:** Project Team (*Including data users for whom signed IUAs are being filed*)

☐ **Section 4:** Data Procurement and Price *(May apply to agents external to the state agency approved by the GMCB for custom extracts or access to the secure data enclave hosted by the GMCB's data consolidation vendor)*

☐ **Section 5**: Data Transmission and Receipt

☐ **Section 6:** Signatures

Required Attachments

☐ **Attachment 1:** Signed Data Use Agreement (*Must be signed by the Authorized User and Principal Investigator*)

Done

☐ **Attachment 2:** Agency's Data Governance and Protection Policies and Procedures

Done

Optional Attachments Applicable to Proposed Re-Disclosures of the Data or Extracts

☐ **Attachment 3**: Copy of proposed or signed State of Vermont contract(s) or any other agreements with external agents requiring re-disclosure of the data set or custom extracts

Not applicable

☐ **Attachment 4:** Project Review Form(s) (PRF) must be filed for every external agent identified under Attachment 3 that will be performing state-directed research requiring use of the data set or extracts of the data set

Not applicable

☐ **Attachment 5:** Data Governance Policies and Procedures for every external agent identified under Attachment 3 that will be receiving and managing the data set or extracts of the data set

Not applicable

Miscellaneous Optional Attachments

☐ **Attachment 6:** If applicable to this application, IRB review and approval documents including internal to your organization **and** AHS IRB Review Committee approval if you responded "No" to the HIPAA criteria cited under Section 1 item 1-5-2.

Done

☐ **Attachment 7:** Other materials requested by the GMCB for the purpose of reviewing the application

Not applicable

APPLICATION

Section 1: Research Summary

Section 1 summarizes the Vermont state agency's research project that may be broad and multi-focused during the term of the DUA. Answer every question in this section. If a question does not apply to your

research project, indicate that the item is "Not Applicable." Do not leave a question blank or the application will be deemed incomplete.

Under Attachment 4 above, state agencies must file PRFs for state-directed research projects that may be more narrowly defined and performed by external entities under contracts, grants, or agreements. Narrowly defined research projects are not summarized in the Project Overview below in Section 1-1 but will be described in the PRFs filed under Attachment 4.

1-1. Project Overview

Authorized User Signatory Name & Title: Gordon Jensen, Senior Associate Dean for Research, University of Vermont College of Medicine
Vermont State Agency Name: University of Vermont College of Medicine
Principal Investigator Name & Title (if different from Authorized User): Charles MacLean, Associate Dean for Primary Care.
Project Name (Should be broad and multi-use to support multiple studies under the DUA): Health Services Analysis using VHCURES at the University of Vermont
Brief Project Description (Summary of subsection 1-5-1): The purpose of this project is to maintain a version of VHCURES at the University of Vermont College of Medicine following established policies that govern data transfer from the vendor, data security, data stewardship, data access, data analysis, data reporting, and communication with the GMCB.
Project Start Date: January 1, 2018. (The current agreement is valid through 12/31/2017)
Project End Date (Term of DUA to be determined by the GMCB): December 31, 2019
Funding Source(s) ☒State ☒Federal ☒ If Other, please describe: UVM Institutional resources
Line of Business data subset(s) included in data request: ☒Commercial ☒Medicaid ☒Medicare

If your state agency intends to re-disclose the data to subcontractor(s) or other external parties, identify parties (Must align with documents filed under Attachment 3): Not applicable

1-2. Authorized User Acknowledgements

Please initial each item indicating your acknowledgement

X	*I agree that I have the authority to sign legally binding agreements on behalf of the organization or institution as applicable to this application and the attached Data Use Agreement (DUA).*
X	*I have read and agree to the terms of the attached DUA including Attachment D to the DUA as applicable to Vermont state agencies. I understand the contents of the attached DUA may only be modified or amended in writing upon mutual agreement of both parties.*
X	*I have read and agree to cooperate with the GMCB to amend the DUA from time to time to the extent necessary for the GMCB to comply with changes to 18 V.S.A. § 9410, HIPAA, or other legal requirements that may apply to the Data Set.*
X	*I understand and agree that I am required to file signed Individual User Affidavits (IUAs) with the GMCB for every individual data user within my organization and those employed by any state contractors, subcontractors or organizations outside my organization approved by the GMCB to access and use the VHCURES data set. I must file the IUAs prior to receipt of the data set and as new users join the project or risk forfeiture of the data set and the DUA.*
X	*I understand and agree that I must obtain the express written approval of the GMCB to release the data set or any derived extracts of the data to any agents or parties outside my organization. I must file a Project Review Form (PRF) with the GMCB for review prior to any re-disclosure of the data set to parties outside of my organization or risk forfeiture of the data and the DUA.*

1-3. Project Questions

Answer the following questions about your research project.

Yes ☐ No☒	Is the project directed by the State of Vermont?
Yes ☒ No☐	Is this project partially or wholly funded by the State of Vermont?
Yes ☐ No☒	Will the project products be used to directly generate revenues and income?
Yes ☒ No☐	Is the project useful for determining the capacity and distribution of existing health care resources?
Yes ☒ No☐	Is the project useful for identifying health care needs and informing health care policy?
Yes ☒ No☐	Is the project useful for evaluating the effectiveness of intervention programs on improving patient outcomes?
Yes ☒ No☐	Is the project useful for comparing costs between various treatment settings and approaches?
Yes ☒ No☐	Is this project useful for providing information to consumers and purchasers of health care?
Yes ☒ No☐	Is this project useful for improving the quality and affordability of patient health care and health care coverage?
Yes ☐ No☒	Does this project directly support public health activities?
Yes ☒ No☐	Does this project support educational purposes such as exploring the claims data for quality, potential uses, health services research training, or integration with other data sets?
Yes ☐ No☒	Does this project propose to link VHCURES data with any other individual record-level data sets? *If yes, describe the data sets and proposed methodology for linking in Section 1-5-4.*
Yes ☐ No☒	Does this project anticipate re-disclosure of the data set, custom extracts or analytical files generated from the data set to any identifiable external agents under contracts, grants, and agreements for research purposes that have been specified? *If yes, complete and file Attachment 3 and Attachment 4: Project Review Form.*

1-4. Requested Data

Indicate the data files requested in this application.

File Type	Commercial Insurers	Medicaid[1]	Medicare[2]	Data Years or Date Range[3]
Medical Eligibility-VT Residents	☒	☒	☒	2007-present

Medical Claims-VT Residents	☒	☒	☒	2007-present
Medical Eligibility- 5% National Sample	Not applicable	Not applicable	☒	2007-present
Medical Claims- 5% National Sample	Not applicable	Not applicable	☒	2007-present
Pharmacy Eligibility	☒	☒	Not applicable	2007-present
Pharmacy Claims	☒	☒	Not applicable	2007-present
Medicare Part D Event- VT Residents	Not applicable	Not applicable	☐	
Medicare Part D Event- 5% National Sample	Not applicable	Not applicable	☐	
Medicare MEDPAR	Not applicable	Not applicable	☐	

[1] *The Department of Vermont Health Access (DVHA) must approve uses and disclosure of Medicaid data.*

[2] *Medicare data may only be used for research directed and partially funded by the state of Vermont.*

[3] *VHCURES data are available on a consolidated CY quarterly or annual basis on paid claims date basis starting with CY 2007.*

1-5. Project Overview

1-5-1. Summarize the purpose and objectives of the proposed research. Describe how the research will contribute to generalizable knowledge applicable to the Vermont population, health, and health care and to the State of Vermont as applicable to the development, implementation, and evaluation of programs administered by Vermont state agencies.

Medical claims analysis is a method increasingly used by health care researchers to better understand health care utilization, treatment choices, and medical expenditures. The purpose of the repository is to create yearly datasets of Vermont patients from Vermont's all-payer claims dataset, the Vermont Healthcare Claims Uniform Reporting and Evaluation System (VHCURES) to be used by researchers at the University of Vermont.

The University of Vermont (UVM) has a data use agreement (DUA) with the Green Mountain Care Board (GMCB) to obtain data from VHCURES. The GMCB is responsible for Vermont's all-payer claims datasets, which include medical and pharmacy claims data, as well as insurance eligibility data for more than 90% of Vermonters. These data allow for population-based analyses of the health care system, and provide a comprehensive, longitudinal look at the changing healthcare landscape in Vermont. The agreement between UVM and the GMCB helps to fulfill the mission of the GMCB to support health services research by supplying datasets to researchers who have the competency and expertise to conduct proposed studies that will ultimately answer important healthcare questions about costs and utilization.

The DUA between UVM and GMCB specifies an administrative structure at UVM which includes an "Authorized User" (Senior Associate Dean for Research currently Gordon Jensen), a "Project Director" (currently Charles MacLean), a "Data Security Director" (currently Jill Jemison), and a "Data Stewardship Committee". The DUA also specifies procedures for proposing research questions that are acceptable to the GMCB based on their federal and state responsibilities.

UVM plans to retain copies of VHCURES datasets managed by the GMCB that have been created on a periodic basis. UVM will add to the repository each time a new dataset is released by the GMCB. These datasets will be made available to researchers at the university who complete the approval process outlined by the DUA with the GMCB. Briefly, the DUA requires researchers to obtain UVM IRB approval, to have their proposal reviewed by a UVM VHCURES Stewardship Committee by submitting a "Scope of Work" document detailing the planned use of the data, to review UVM and GMCB data security requirements and sign required user affidavits, and to have their proposal reviewed by the GMCB data governance council or its designees.

Researchers at UVM using VHCURES via this repository will be overseen by the Data Stewardship Committee and by the Project Director identified in the DUA, who is named as the Principal Investigator of this IRB protocol. Data acquisition (receiving data from the GMCB) and data distribution (creating datasets for use by specific UVM researchers) will be tracked. Analytic products created from analyses using VHCURES data will also be monitored to ensure that such products (e.g., figures, tables) meet GMCB rules for data security and suppression of small cell sizes. Data supplied to researchers from the repository will be restricted to only the requested and proposal-approved variables.

The DUA also requires that once individual research projects are completed, the data extracts used in the analyses be either returned or destroyed.

The lifecycle of each individual project using the repository will be tracked on a secure website to be accessed by the Project Director, Data Security Director, and GMCB to review the progress of researchers and track project open and close dates.

1-5-2. If your project requires the use of Medicaid data, is the research intended to support public health activities? If yes, explain the application of the project to public health. If no, you may be required to obtain approval to use the Medicaid data from the AHS IRB Review Committee in addition to DVHA. See Optional Attachment 6.

The research is not intended to support public health activities.

1-5-3. Summarize the credentials, skills, and experience of the Principal Investigator and key research staff that are evidence that the Data Set will be used to conduct and support systematic investigations guided by expertise in the subject matter and research methods,

including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

The Principal Investigator is an experienced health services researcher who has served in the role of PI for the UVM-VHCURES project and the Chair of the UVM VHCURES Data Stewardship Committee for the past two years. The current active research team is led by Valerie Harder, an experience and funded health services research in the Department of Pediatrics. The staff supporting the project in General Internal Medicine, the Dean's office, and the College of Medicine Technology Services are knowledgeable, skilled, and have a two year track record of project management of this project.

1-5-4. Explain how you will ensure that your organization and external agents performing state-directed research will have access to the minimum necessary data to support specified research purposes and projects.

The Scope of Work form and the internal review by the Data Stewardship Committee and the UVM IRB assure that minimum necessary data are requested and received.

1-5-5. List and briefly describe any unidentifiable or identifiable record-level data files you are planning to use in conjunction with the requested data. If the files will be linked explain the methodology for linking the data and how the identity of individuals and their PHI will be protected from disclosure.

Data linking is not requested at this time.

1-5-6. Identify and briefly describe the funding source(s) for the proposed research including both internal and external sources that may be in the form of state and federal funding and grants. Describe the relationship between the funding source(s) and your organization.

Maintenance of the VHCURES dataset at UVM is supported by the Dean's Office, which includes funding of College of Medicine Technology Services. As noted on the Scope of Work form: for all UVM projects regardless of project funding source, State funds come to the College of Medicine each year to support a variety of activities. We have dedicated a portion of these funds to support VHCURES and other CMS-based projects. This support is specified in four ways: 1) 3% of the College of Medicine Senior Associate Dean for Research's salary to support her/his role as Authorized Institutional User; 2) 3% of the College of Medicine Director of Technology Services' salary to support her/his role as Data Custodian and Security Director; 3) 3% of the salary of the UVM COM faculty member designated as the Project Director; and 4) 10% of the College of Medicine Technology Services Systems Administrator designated to receive and perform initial processing on the VHCURES/CMS data

1-5-7. Explain whether any component of the project was review and approved by an Institutional Review Board (IRB). If yes, attach the IRB review and approval under Attachment 7 to this application.

Yes, this project is approved by the UVM IRB. The most recent annual renewal was completed on October 10, 2017.

Section 2: Data Management Plan

Section 2 relates to the policies and procedures your organization will use to ensure the proper management of the VHCURES standard comprehensive research data set and custom extracts derived from the data set. The GMCB recognizes the applicability of best practices for information security and privacy used in the CMS Data Privacy Safeguard Program (DPSP)[1] to the review of VHCURES DUA applications. Respond to every question about your organization's and those of approved entities external to your organization policies and procedures to ensure technical and administrative safeguards over the data.

Please answer the questions in each section with references to any attached documents including relevant page and/or section numbers. **Do not simply cite a cross-reference to the policy and procedure documents included under Attachment 2 and 5 of this application in lieu of answering each question. If questions are not answered completely, the application will be deemed incomplete.**

Any Project Review Forms (PRF) filed with this application for external agents under Attachment 4 may cite cross-references to this application for the same items in Section 2 below. Instructions are included on the PRFs.

[1] "Data Privacy Safeguard Program Information Security and Privacy Best Practices" listed under Additional Resources published on https://www.resdac.org/resconnect/articles/158

2-1. Physical Possession and Storage of Data Files

Include specific references to the Data Governance and Protection policies and procedures documents filed with this application under Attachments 2 and 5 in your responses to the items below. ***Do not simply cite a cross-reference to the policy and procedure documents in lieu of answering each question.***

2-1-1. Describe how your organization will maintain an accurate and timely inventory of the VHCURES standard comprehensive research data set including original files received and any derived files used within your organization or released to external agents under state contracts and agreements.

Data are received by the College of Medicine Technical Services department under the direction of the Data Custodian and Security Director (currently Jill Jemison) and maintained behind a strict firewall with continuously updated security strategies.

2-1-2. Describe how your organization will ensure and monitor the compliance of all members of research teams both in-house and those employed by approved external agents with privacy and security policies and procedures as described in the documentation filed under Attachments 2 and 5 to this application and as required by the DUA.

Members of the research teams are monitored by the Data Stewardship Committee (on which the Data Custodian and Security Director sits), by the IRB, and by the principal investigators responsible for the individual approved projects.

2-1-3. Describe the procedures your organization will take to track the status and roles of the research team and notify GMCB of any project staffing changes.

Status and roles of team members is managed through the central authentication for access to all systems at the College of Medicine—this is completed through the College of Medicine Technical Services. Additionally, staffing changes are required to be reported to the IRB. The principal investigators for each individual project is also responsible for reporting staffing changes on their project.

2-1-4. Describe your organization's training programs that are used to educate staff on how to protect sensitive data with personally identifiable information, protected health information, and other sensitive financial, socioeconomic, and personal information.

All research faculty and staff must complete on online training in Human Subjects protection every three years; this is overseen and tracked by the UVM IRB. For investigators requesting access to VHCURES data, an in-person educational session and interview with a member of the Data Stewardship Committee are required.

2-1-5. Describe the protocol that would be followed by your organization or that of approved external agents, if applicable, to report and mitigate a breach in the security of the data set. Who will be responsible for notifying the GMCB (and CMS as applicable to Medicare data) of any suspected incidents of a breach in the security of the VHCURES data?

The Principal Investigator is the primary person responsible for this reporting. If unavailable, the Data Custodian and Security Director, or the Authorizing User are responsible.

2-1-6. What actions will your organization and approved external entities take to physically secure the data files? This includes files in motion, or on servers, local workstations, and hard media.

We will follow practices established by the Data Custodian and Security Director, and expect these to evolve with best practice approaches. As noted on the Scope of Work document: In

order to support the security requirements for our most sensitive data, The University of Vermont College of Medicine has deployed SEDRC, a Secure Environment for Data and Research Computing. SEDRC systems are configured based on one of three security tiers (confidential, restricted, and prohibited) as defined by UVM information security policies. The VHCURES data is housed within this environment on Prohibited systems, the most secure. Prohibited systems require that data is stored on encrypted volumes, transferred over encrypted connections, and cannot leave the environment unless approved by the VHCURES Data Stewardship Committee. Three systems have been deployed to support VHCURES: An analytics server running statistical software, a data storage server running Microsoft SQL, and a secure file transfer server running Accellion kiteworks. In order to gain access to these systems approval from the VHCURES Data Stewardship Committee is required.

2-1-7. Please explain if your organization intends to transmit, store, or transfer the data set or any derived files outside the continental United States.

Not applicable

2-2. Data Sharing, Electronic Transmission, Distribution

Include specific references to the Data Governance and Protection policies and procedures documents filed with this application under Attachments 2 and 5 in your responses to the items below. ***Do not simply cite a cross-reference to the policy documents in lieu of answering each question.***

2-2-1. Describe what your organization's policies and procedures will be for sharing, transmitting, and distributing the VHCURES data set and any derived files.

The full VHCURES dataset is stored on an SQL Server that is only accessible by approved system administration personnel. Approved extracts of the VHCURES data are placed on a secured server that is only accessible using Microsoft's Remote Desktop through a Virtual Private Network (VPN) that requires multifactor authentication. Folders are created for each specific project and only those users who have been provided by the PI listed on the Data Use Agreement can access these folders. Users who leave the project have permissions immediately revoked as appropriate.

Access to the server is logged in the security event logs which can be accessed upon request with appropriate authorization for auditing. Review of project staff/folder access is periodically checked and confirmed with the PI.

The VCHURES data will not be shared, transmitted or distributed. Only summary tables approved by the GMCB will be shared/published.

2-2-2. The GMCB's preferred method of transmission of the data files is through a secure File Transfer Protocol (SFTP) transmission. If you anticipate requesting encrypted hard media, please explain the reasons that SFTP is not an option.

Not applicable.

2-2-3. Would your organization and approved external agents be interested in accessing a hosted data enclave or a researchers' workbench environment eliminating the transmission of data files via SFTP or via encrypted hard media outside of the hosted enclave? If yes, would the interest hold if there are fees for this service? If not interested at all or cautious, please explain your concerns.

Our preference is to house the data on our own system. This give us flexibility to use a variety of analytic tools. We would be interested in hearing more about a hosted enclave. Some of our faculty have experience in this area.

2-2-4. Describe your organization's methods and those of approved external agents for tracking, monitoring, and auditing access and use of sensitive data such as the VHCURES data set.

Access in monitored by housing the data in a single environment where access can be monitored, tracked and audited.

2-2-5. Describe the policies and procedures and procedures your organization and approved external agents use to define data access privileges for individual users of the data, including the Principal Investigator, Data Custodian, analysts and researchers, administrative support, and IT support.

Access to VHCURES is granted by the Data Stewardship Committee based on submission and approval of a research project which also must be approved by the IRB and by the GMCB.

2-2-6. Explain the use of technical safeguards for data access (which may include password protocols, log-on/log-off protocols, session time out protocols, and encryption for data in motion and data at rest).

See section 2.1.6 above which describes the security and technical safeguards.

2-2-7. If approved external agents will have access to the data please describe how that organization's analysts will access the data file, e.g., VPN connection, travel to your organization, or house the data at other locations.

Not applicable

2-2-8. If additional copies of the data will be housed in separate locations, list the locations and describe how the data will be transferred to these locations.

Not applicable

2-3. Data Reporting and Publication

2-3-1. Explain your process for reviewing publications prior to dissemination to ensure accurate and appropriate representation of your data sources, analytic methodology, results, caveats, and disclaimers. Describe how your publications will be reviewed to ensure compliance with requirements in the DUA addressing small n suppression, disclaimer of any GMCB endorsement of findings, and data source citation.

Data summaries and tables are submitted for approval to the GMCB via the *UVM-VHCURES Commons* secure website.

2-4. Completion of Research Tasks and Data Destruction

2-4-1. Describe how you will complete the Certificate of Data Destruction for the data set and derived files stored by your organization or by approved external agents and how the data will be deleted, destroyed or rendered unreadable by all parties with access to the files upon completion of the project.

Return or destruction of the data are carried out by staff under the direction of the Data Custodian and Security Director and the certificate is posted to the *UVM-VHCURES Commons* secure website for review by the GMCB.

2-4-2. Describe your organization's policies and procedures and those of external agents used to protect VHCURES data files when individual staff members of research teams terminate their participation in research projects (which may include staff exit interviews, return of passkeys, and immediate access termination for example).

The UVM organizational policies govern access to buildings and computer systems.

2-4-3. Describe your organization's policies and procedures to ensure original or derived data files, including non-published aggregate reports, are not used following the completion of the project.

Original and derived data files, and non-published aggregate reports are returned or destroyed at the end of the project. If materials are in the "returned" state, a PI must generate a new request to access them.

Section 3: Project Team

In Section 3-5, list the anticipated individual users, their respective organizations including state agencies and external agents such as state contractors and subcontractors, and project roles. **Signed IUAs for individual users within your organization and those employed by external entities accessing the data must be filed prior to receipt of the VHCURES data set.**

3-1. Authorized User (State Agency)

Please provide contact information for the Authorized User's signatory.

Name and Title of Signatory for the Authorized User		
Gordon Jensen		
Organization Name		
University of Vermont		
Street Address		
89 Beaumont Avenue		
City	State	Zip
Burlington	VT	05401
Telephone	Email	
802 656 2156	Gordon. jensen@med.uvm.edu	

3-2. Principal Investigator (State Agency)

Please provide contact information for the PI if different person than the AU.

☐Same as Authorized User Signatory

Name and Title of Principal Investigator		
Charles MacLean		
Organization Name		
University of Vermont		
Street Address		
89 Beaumont Ave		
City	State	Zip
Burlington	VT	05401
Telephone	Email	
802 656-8250	Charles.maclean@uvm.edu	

3-3. Data Custodian(s)

Provide contact information for the data custodian for your organization and the data custodians for any external agents such as state contractors, subcontractors or other organizations that will storing the VHCURES data set or derived files.

Name and Title of Data Custodian (State Agency)		
Jill Jemison		
Organization		
University of Vermont		
Street Address		
89 Beaumont Ave		
City	State	Zip
Burlington	VT	05401
Telephone	Email	
802 656-0076	Jill.jemison@med.uvm.edu	

3-4. Individual Users

Identify all individuals from state agencies and external agents who will be participating on this project. These individuals may be project managers, analysts, IT professionals, or any other person who may have access to row-level data or aggregate reports prior to the suppression of small n. You must attach a signed individual user affidavit for each of these individual users prior to the receipt of the data after the DUA is approved including any users not identified on this list when this application was submitted.

Name	Organization	Project Role or Title
Valerie Harder	UVM	Principal Investigator
Susan Richardson	UVM	Research Analyst
Judith Shaw	UVM	Research Executive Director
Charles MacLean	UVM	Principal Investigator
Richard Wasserman	UVM	Professor of Pediatrics
Keith Robinson	UVM	Director for Quality, UVM Children's Hospital
Mathew Hollander	UVM	Assistant Professor of Pediatrics
Lindsay Van Leir	UVM	Research Specialist

Section 4: Data Procurement and Price

There will be no fee charged to state agencies that receive the data set via a secure file transfer protocol (SFTP) or encrypted hard media, if approved by the GMCB. The authorized user will receive the data from the GMCB's designated data processing vendor.

In the future, the GMCB may be offering access to the data through a hosted data enclave. This would eliminate or be an additional option for accessing the data via electronic SFTP transmission of the record-level data. GMCB will notify the authorized user for the DUA when this service becomes available as an option and how it will work as to number of user seats and pricing.

There may be fees for custom extracts generated from the standard comprehensive research data set as requested by the state agency. Typically, custom extracts are generated to support the data stewardship principle of disclosing the minimum necessary data to support the research purpose. Data users may be authorized to access a secured data enclave hosted by the vendor. Use of services provided by the GMCB's data consolidation vendor may require payment of a fee to the vendor. Fees will be determined by GMCB a case-by-case basis. Onpoint Health Data will manage any invoicing for fees.

The GMCB's designated vendor for the VHCURES Standard Comprehensive Research Data Set and custom extracts is:

Onpoint Health Data

Mailing Address:
75 Washington Avenue, Suite 1E
Portland, ME 04101

Physical Address:
55 Washington Avenue
Portland, ME 04101

Main Phone: (207) 623-2555

www.onpointhealthdata.org

Section 5: Data Transmission and Receipt

Use of an electronic secure File Transfer Protocol is the preferred mode of release for approved data extracts. Onpoint Health Data, the GMCB's data consolidation and warehousing vendor will provide an "Electronic Data Transmission Readiness and Logistics Checklist" to assist you in determining whether you are able to receive the transmission.

Please identify your primary contact below for setting up the logistics for SFTP transmission of the approved data extract. The primary contact must either be the Authorized User or Principal Investigator or Data Custodian identified on the DUA or be designated by the AU or PI.

As noted under Section 4, the GMCB may offer access to the data via a hosted data enclave in the future. Authorized users will be notified when this service becomes available.

Primary Contact for Planning Data Transmission Logistics

Name: Stephen Goldman **Title/Role in the Project: Manager, Data and Application Services**
If not AU, PI or DC, designated by: Jill Jemison
Email Address: Stephen.goldman@med.uvm.edu
Phone Number: 802-656-9770
Organization/Agency Affiliation: University of Vermont Larner College of Medicine
Street, City, ZIP Address: 89 Beaumont Ave., Burlington, VT 05405

Section 6: Signatures

All statements made in this application are true, complete, and correct to the best of my knowledge.

Authorized User Name: GORDON JENKEN	
Signature:	Date: Nov. 22, 2017
Principle Investigator Name (if different from Authorized User) CHARLES MACLEAN	
Signature:	Date: 11.20.17
Data Custodian Name: JILL JEMISON	
Signature:	Date: 11/20/17

GMCB Processing Section

For GMCB Use Only

Applicant Organization or Entity Name:

Data Types: Commercial ( ) Medicaid ( ) Medicare ( )

Application Receipt Date/GMCB Initials:

Date Application Deemed Complete:

DVHA Application Approval Date:

GMCB Application Approval Date/GMCB Initials:

Date Applicant Notified of Approval:

Application Disapproval Date:

Date Applicant Notified of Disapproval/GMCB Initials

Summary of reasons for disapproval:

Date Application Deemed Incomplete/GMCB Initials:

Date Applicant Notified Application Deemed Incomplete:

Summary of reasons the application deemed incomplete:

Date Application Deemed Incomplete Resubmitted:

DVHA Application Approval Date:

GMCB Resubmitted Application Approval Date /GMCB Initials:

Date Applicant Notified of Approval of Resubmitted Application:

Resubmitted Application Disapproval Date/GMCB initials:

Summary of reasons for disapproval:

Green Mountain Care Board

89 Main Street
Montpelier, VT 05620-3101
(802) 828-2177
http://gmcboard.vermont.gov

GMCB USE ONLY
DUA #:
Authorized User: State Entity [ ]; Non-State Entity [ ]
Data: Commercial [ ]; Medicare [ ]; Medicaid [ ]
DUA Start Date:
DUA End Date:
AOA Approval Date:
AGO Approval Date:

Data Use Agreement for Release of a VHCURES Limited Use Health Care Claims Research Data Set

1. Parties

This agreement is made and entered into by and between the GMCB and _____ University of Vermont, hereinafter referred to as "the Authorized User," for the Project Title[1]: Health Services Analysis using VHCURES at the University of Vermont.

2. Definitions

For purposes of this Agreement,

A. "Agent" means any individual or entity (e.g., a contractor, subcontractor, grantee, or subgrantee) acting on behalf of the Authorized User and subject to the Authorized User's control or accessing the Data Set on behalf of the Authorized User.

B. "Agreement" means this data use agreement detailing the Authorized User's commitment to data privacy and security and setting forth restrictions, limitations, and conditions on the use and disclosure of the Data Set. The Agreement includes the following attachments:

1. the GMCB's data use agreement with CMS (Attachment A)
2. the GMCB's data use agreement with DVHA (Attachment B);
3. the Application, including the Authorized User's Data Governance Policies and Procedures and all other attachments to the Application (Attachment C); and
4. for Vermont agencies, the Vermont Agency Addendum (Attachment D).

C. "Application" means the Authorized User's Application for Access to VHCURES Limited Use Health Care Claims Research Data Set, as filed with and approved by the GMCB and, if applicable, DVHA.

[1] The Project Title will be provided by the GMCB based on the Application.

D. "Authorized User" means the individual or entity being given access by GMCB, and in the case of the Medicaid data subset, by DVHA, to the Data Set pursuant to this Agreement.

E. "CMS" means the Centers for Medicare & Medicaid Services.

F. "Data Set" means the VHCURES Limited Use Health Care Claims Research Data Set being released to the Authorized User, and all data therein.

G. "Disclose" means to release, transfer, provide access to, or divulge in any manner information outside of the entity holding the information.

H. "DVHA" means the Department of Vermont Health Access.

I. "GMCB" means the Green Mountain Care Board established in Title 18, chapter 220 of the Vermont Statutes Annotated.

J. "HIPAA" means the Health Insurance Portability and Accountability Act of 1996, including the Standards for the Privacy of Individually Identifiable Health Information at 45 CFR Parts 160 and 164 ("Privacy Rule") and the Security Standards at 45 CFR Parts 160 and 164 ("Security Rule"), as amended by subtitle D of the Health Information Technology for Economic and Clinical Health Act.

K. "IUA" means an Individual User Affidavit, a form maintained by the GMCB.

L. "Non-State Entity" means an individual or entity that is not a Vermont State Entity.

M. "Principal Investigator" means the individual designated by the Authorized User to be responsible for ensuring compliance with the requirements in this Agreement. The Authorized User may also be the Principal Investigator.

N. "Research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

O. "State" means the State of Vermont, including the GMCB.

P. "Vermont State Entity" means a Vermont State agency or a contractor or other organization performing research that is directed and partially funded by the State of Vermont.

Q. "VHCURES" means the Vermont Health Care Uniform Reporting & Evaluation System, a health care database maintained by the GMCB pursuant to 18 V.S.A. § 9410.

3. Authority and Purpose

Pursuant to 18 V.S.A. § 9410, the GMCB maintains certain health care claims and eligibility data within VHCURES to enable it to carry out its statutory duties, including

A. determining the capacity and distribution of existing resources; identifying health care needs and informing health care policy;

B. evaluating the effectiveness of intervention programs on improving patient outcomes; comparing costs between various treatment settings and approaches;

C. providing information to consumers and purchasers of health care; and

D. improving the quality and affordability of patient health care and health care coverage.

To the extent allowed by HIPAA, and pursuant to Regulation H-2008-01, the GMCB seeks to make some of this data available as a resource for individuals and entities to continuously review health care utilization, expenditures, and performance in Vermont. The purpose of this Agreement is to specify the conditions under which the GMCB will release this data and to ensure that the data is accessed, maintained, used, and disclosed in compliance with all applicable statutory, regulatory, and contractual requirements.

4. Data Referenced by this Agreement

Claims and eligibility data that may be available under a data use agreement can be broadly grouped into three lines of business, commercial, Medicaid, and Medicare. The GMCB has independent discretion to manage data for the commercial line of business, while DVHA and the GMCB share discretion with respect to the Medicaid line of business. DVHA must approve the use and disclosure of Medicaid data and, if the Authorized User will be receiving Medicaid data, DVHA must sign this Agreement. Per an agreement with CMS, Medicare data is available only to Vermont State Entities.

The table below identifies the types of data that will be disclosed to the Authorized User under this Agreement.

FOR GMCB USE ONLY

File Type	Commercial Insurers	Medicaid	Medicare
Medical Eligibility	☐	☐	☐
Medical Claims	☐	☐	☐
Pharmacy Eligibility	☐	☐	Not applicable
Pharmacy Claims	☐	☐	Not applicable
Medical Eligibility- 5% Medicare National Sample	Not applicable	Not applicable	☐
Medical Claims- 5% Medicare National Sample	Not applicable	Not applicable	☐
Medicare Part D Event- VT Residents	Not applicable	Not applicable	☐
Medicare Part D Event- 5% National Sample	Not applicable	Not applicable	☐
Medicare MEDPAR	Not applicable	Not applicable	☐

5. Responsibilities of the Principal Investigator

The Principal Investigator will act as the steward of the Data Set, including, but not limited to,

A. ensuring that the GMCB has an IUA on file for each person that will be given access to the Data Set and that each such person understands and observes all the restrictions, limitations, and conditions specified in this Agreement;

B. ensuring appropriate safeguards are implemented to protect the confidentiality of the Data Set and prevent its unauthorized use or disclosure;

C. tracking and reporting to the GMCB on the uses and disclosures of the Data Set, including notifying the GMCB and, if appropriate, CMS, of any unauthorized uses or disclosures;

D. seeking and obtaining the consent of the GMCB and, when applicable, DVHA, before disclosing the Data Set to an Agent or to any other entity not identified in the Application as the data user; and

E. providing the GMCB with copies of any materials that contain data from the Data Set or information derived from the Data Set prior to its publication or release.

The Principal Investigator may delegate technical responsibility to other personnel within Authorized User's organization, as identified in Attachment C to this Agreement, for the implementation of appropriate safeguards to protect the confidentiality of the Data Set and to prevent its unauthorized disclosure or use.

6. Restrictions, Limitations, and Conditions of Use and Disclosure

The Authorized User, by and through the Principal Investigator, will ensure compliance with the following restrictions, limitations, and conditions:

A. The Authorized User may not use, sell, disseminate, or otherwise disclose the Data Set or any derivative data, including statistical tabulations derived from the data,

   i. in a manner that is contrary to law; or

   ii. for purposes other than those expressly specified in the Application and permitted by this Agreement, without the express written consent of the GMCB and, if applicable, DVHA.

B. The Authorized User may not disclose the identity of enrollees, members, beneficiaries, patients, employer groups, purchaser groups, or abortion services providers and may not disclose any direct findings, listings, or other information that could be used to identify one or more of these individuals or groups.

C. The Authorized User must obtain the express written approval of the GMCB before attempting to link the Data Set in any manner with other data containing personally identifiable information that may enable the identification of enrollees, members, beneficiaries, patients, employer groups, purchaser groups, providers of abortion services, or physicians.

D. The Authorized User may not disclose, with or without direct physician identifiers, direct findings, listings, or information derived from Medicare data, if such findings, listings, or information can, by themselves or in combination with other data, be used to deduce a physician's total Medicare reimbursements.

E. Prior to calculating aggregated values based on observations or elements, the Authorized User must censor any cell in a data table with a count of 10 or fewer along with another cell in the same row and another cell in the same column to prevent the identification of the cell with a count or 10 or fewer in a table.

F. The Authorized User may not decrypt or attempt to decrypt any encrypted data for any purpose or disclose any information that has been encrypted or removed from the Data Set.

G. The Authorized User may not produce, publish, disseminate, or make public any information that could be used to determine or ascertain information about insurers or providers that would be deemed proprietary, such as the amount paid by identified insurers or to identified providers for individual procedure codes. This prohibition on public reporting is not applicable to reporting paid amounts at aggregate service levels such as service bundles, episodes of care, and other types of service aggregations.

7. Safeguards

The Authorized User must implement and use appropriate safeguards to protect the confidentiality of the Data Set and prevent its unauthorized use or disclosure. The Authorized User must comply with all applicable requirements of HIPAA, including 45 C.F.R. sections 164.308 (administrative safeguards), 164.310 (physical safeguards), 164.312 (technical safeguards), and 164.316 (policies and procedures and documentation requirements).

8. Review of Publications

Unless a different time period is specified by the GMCB, the Authorized User must provide the GMCB a preview copy of any materials proposed to be published or otherwise disclosed at least fifteen (15) business days prior to publication or disclosure, if the materials contain data from the Data Set or information derived from the Data Set (this includes materials understood by the Authorized User to be consistent with the uses stated in the Application). The GMCB will review the proposed materials and determine whether they comply with all pertinent provisions of this Agreement.

9. Reporting

The Authorized User must file periodic reports, at times specified by the GMCB, with updated information on

A. the status of each individual data user for whom an IUA has been filed;

B. proposed new users that will require access to the Data Set and who will be filing IUAs prior to gaining access to the Data Set; and

C. details about data disposition and location, as required by the GMCB.

10. Attribution

The Authorized User must acknowledge the GMCB and VHCURES as the source of the data in any public reports, publications, presentations, or other materials generated from the Data Set.

The Authorized User must prominently state in written materials, publications, and presentations that the analyses, conclusions, and recommendations drawn from the Data Set are solely those of the Authorized User or the Principal Investigator and are not necessarily those of the GMCB.

11. Minimum Necessary

Within its organization and the organizations of its Agents, the Authorized User will limit access to the Data Set to the minimum number of individuals, data elements, and records necessary to achieve the research purposes described in the Application or in a contract for research services approved by GMCB for a re-disclosure under an existing DUA.

12. Notification of Unauthorized Access, Uses and Disclosures; Mitigation

A. The Authorized User must immediately report to the GMCB whenever it becomes aware or has reason to suspect that the Data Set has been accessed, used, or disclosed in a way that is not permitted by state or federal law or that otherwise violates the terms of this Agreement.

B. In addition to the requirements of subsection A of this section, the Authorized User must report any release, disclosure, or publication of personally identifiable information (PII) from the Medicare data, including loss of these data or disclosure to any unauthorized persons, as a potential security or privacy breach to the GMCB and to the CMS Action Desk by telephone at (410) 786-2580 and by e-mail notification at cms_it_service_desk@cms.hhs.gov within one hour of the discovery of the breach by any individual data user, including the Principal Investigator and must cooperate fully in the federal security incident process.

C. The Authorized User must mitigate, to the extent practicable, any harmful effect that is known to it of an impermissible use or disclosure of the Data Set. The Authorized User shall draft and carry out a plan of corrective action to address any incident of impermissible use or disclosure of the Data Set. If requested by the GMCB, the Authorized User shall make its mitigation and corrective action plans available to the GMCB.

13. Ownership

The Data Set is the sole property of the GMCB, or, where applicable, DVHA or CMS. The Authorized User has a license to use the Data Set pursuant to this Agreement only for the term established herein and does not obtain any right, title, or interest in the Data Set.

14. Reliance on Representations

The Authorized User represents that it is authorized to bind all individuals who may have access to the Data Set to the terms of this Agreement.

The Authorized User represents that the facts and statements made in the Application are complete and accurate and represent the total uses to which the Data Set will be put. The Authorized User further represents that the Data Set is the minimum amount of data necessary to achieve the purposes described in the Application.

The disclosure of the Data Set to the Authorized User is being made in reliance upon the accuracy of all representations made by the Authorized User, including the representations made by the Authorized User in the Application.

15. Termination of Individual Users' Access; Certificates of Destruction

The Authorized User must notify the GMCB at least fifteen (15) days prior to the date an individual user will no longer need access to the Data Set and follow procedures to ensure that the individual user's access has been terminated by this date.

The Authorized User must file certificates of data destruction with the GMCB for terminated users with data or data tables that were generated using the Data Set and were stored in distributed data systems external to the Authorized User.

16. Disclaimer of Warranties

The GMCB makes no warranty concerning the accuracy of the Data Set or its fitness for any particular purpose.

17. Sub-Agreements

The Authorized User may not assign any of its rights or obligations under this Agreement or disclose the Data Set to an Agent without the prior written approval of GMCB, and where applicable, DVHA. The Authorized User must notify the GMCB at least thirty (30) days prior to disclosing the Data Set to an Agent and must provide the GMCB with the following information:

A. an electronic copy of the agreement between the Authorized User and the Agent;

B. an IUA for each proposed data user; and

C. any other information requested by the GMCB.

The Authorized User must ensure that any Agent to whom the Authorized User or Principal Investigator provide the Data Set is bound by a written agreement to the same restrictions and conditions that apply to the Authorized User and Principal Investigator under this Agreement. The written agreement must identify the GMCB and, if applicable, DVHA, as direct and intended third-party beneficiaries with the right to enforce any breach of the agreement upon request.

The Authorized User shall be responsible and liable for any use, publication, or other disclosure or release of the Data Set by any of its Agents.

18. Insurance

Before receiving the Data Set, the Authorized User must provide certificates of insurance to show that the following minimum coverages are in effect: IT Professional Liability or Technology Professional Liability insurance with minimum third-party coverage of $1,000,000.00 per claim, $2,000,000.00 aggregate; and first party Breach Notification Coverage of not less than $2,000,000.00. With respect to the first party Breach Notification Coverage, the Authorized User shall name the State of Vermont and its officers and employees as additional insureds for liability arising out of this Agreement.

19. Defense and Indemnity

The Authorized User shall defend the State and its officers and employees against all third-party claims or suits arising in whole or in part from any act or omission of the Authorized User or of any Agent of the Authorized User in connection with their receipt, use, disclosure, or other involvement with the Data Set. The State shall notify the Authorized User in the event of any such claim or suit, and the Authorized User shall immediately retain counsel and otherwise provide a complete defense against the entire claim or suit. The State retains the right to participate at its own expense in the defense of any claim. The State shall have the right to approve all proposed settlements of such claims or suits. In the event the State withholds approval to settle any such claim, then the Authorized User shall proceed with the defense of the claim but under those circumstances, the Authorized User's indemnification obligations shall be limited to the amount of the proposed settlement initially rejected by the State.

After a final judgment or settlement the Authorized User may request recoupment of specific defense costs and may file suit in Washington Superior Court requesting recoupment. The Authorized User shall be entitled to recoup costs only upon a showing that such costs were entirely unrelated to the defense of any claim arising from an act or omission of the Authorized User or of the Authorized User's Agent.

The Authorized User shall indemnify the State and its officers and employees in the event that the State, its officers or employees become legally obligated to pay any damages or losses arising from any act or omission of the Authorized User or of an Agent of the Authorized User in connection with their receipt, use, disclosure, or other involvement with the Data Set.

The Authorized User agrees that in no event shall the State be obligated to defend or indemnify the Authorized User or otherwise be liable for the expenses or reimbursement, including attorneys' fees, collection costs or other costs of the Authorized User except to the extent awarded by a court of competent jurisdiction.

20. Sovereign Immunity

The State reserves all immunities, defenses, rights or actions arising out of the State's sovereign status or under the Eleventh Amendment to the United States Constitution. No waiver of the State's immunities, defenses, rights or actions shall be implied or otherwise deemed to exist by reason of the State's entry into this Agreement.

21. Term

This Agreement shall terminate at 12:00 a.m. on _____ ("Termination Date"), unless the GMCB approves an alteration or extension prior to the Termination Date.

A Vermont State Agency shall be granted a term of two (2) years from the date of execution, and must reapply at least sixty (60) days prior to termination to ensure continuous access to data. Failure to submit new DUA applications to the GMCB in a timely and complete manner may result in gaps in access to data while the application is under review.

Authorized Users who are Non-State Entities shall notify the GMCB at least sixty (60) days prior to the termination date specified in this DUA with a request to extend the retention period for the Data Set. The Authorized User shall file any information required by GMCB pertaining to a request to extend the retention period in a timely and complete manner. The term of any extension is wholly at the discretion of GMCB, which may also deny the request and require the Authorized User to file an Application for a new DUA. A DUA may not be extended more than once.

22. Enforcement; Penalties

In addition to or in lieu of termination under section 21 of this Agreement, in the event that the Authorized User, a Principal Investigator, or an individual data user fails to adhere to the terms of this Agreement, the GMCB and, when applicable, DVHA and/or CMS, may take any or all of the following actions: recall some or all of the data; revoke the Authorized User's permission to use the data; and pursue civil and criminal sanctions under applicable state and federal laws and regulations. The following are examples of civil and criminal sanctions that may apply:

A. 18 V.S.A. § 9410, providing for the assessment of administrative penalties of up to $1,000 per violation for knowing violations of the statute; up to $10,000 per violation for willful violations of the statute; and up to $50,000 per violation for knowing failures to comply with the confidentiality requirements of the statute or confidentiality rules adopted pursuant to the statute through use, sale, or transfer of the data or information for commercial advantage, pecuniary gain, personal gain, or malicious harm.

B. 33 V.S.A. § 1902a, providing for assessment of an administrative penalty of up to $1,000 for a first violation and up to $2,000 for any subsequent violation.

C. Section 1106(a) of the Social Security Act, providing for a fine not exceeding $10,000 or imprisonment not exceeding 5 years, or both, for disclosures of information covered by § 1106 that are not authorized by regulation or by Federal law.

D. 5 U.S.C. § 552a(i)(3) (Privacy Act), providing that a person who knowingly and willfully requests or obtains any record concerning an individual from an agency under false pretenses is guilty of a misdemeanor and may be fined not more than $5,000.

E. 18 U.S.C. § 641, providing for criminal penalties and fines for unlawfully taking or converting data or file(s), or receiving data or file(s) knowing that they were stolen or converted.

23. Location of Data Set

The Data Set may not be transmitted, stored, or transferred by any means outside the continental United States without the express written permission of the GMCB and, if applicable, DVHA.

24. Destruction of the Data Set; Certificates of Destruction

The Authorized User must ensure that the Data Set is deleted, destroyed, or otherwise rendered unreadable, as directed by the GMCB, by the Termination Date set forth in Section 21 of this Agreement or thirty (30) days after the Data Set is no longer needed for the purposes described in the Application, whichever occurs first. The Principal Investigator shall certify that the Data Set has been deleted, destroyed, or otherwise rendered unreadable by submitting a written certificate of destruction to the GMCB, and when applicable, DVHA.

25. Amendment

This Agreement may only be modified or amended in writing upon mutual agreement of both parties. The Authorized User shall cooperate with GMCB to amend this Agreement from time to time to the extent necessary for the GMCB to comply with changes to 18 V.S.A. § 9410, HIPAA, or other legal requirements that may apply to the Data Set.

26. Interpretation

Any ambiguity, conflict, or inconsistency in the Agreement shall be resolved to require compliance with 18 V.S.A. § 9410, HIPAA, and other legal requirements that may apply to the Data Set.

In interpreting this Agreement, the order of precedence shall be as follows:

A. The Vermont State Entity Addendum (Attachment D), if any;

B. This Agreement;

C. The Agreement between the GMCB and CMS (Attachment A);

D. the Agreement between the GMCB and DVHA (Attachment B); and

E. The Authorized User's Data Governance Policies and Procedures (Attachment C).

27. Governing Law, Jurisdiction, and Venue

This Agreement will be governed by the laws of the State of Vermont. Any action or proceeding brought in connection with this Agreement shall be brought and enforced in the Superior Court of the State of Vermont, Civil Division, Washington Unit. The Authorized User irrevocably submits to the jurisdiction of this court for any action or proceeding regarding this Agreement.

28. Counterparts; Execution

Vermont Healthcare Claims Uniform Reporting and Evaluation System (VHCURES)
Limited Use Health Care Claims Research Data Set
Data Use Agreement (DUA)

This Agreement may be executed in counterparts and the exchange of signature pages to this Agreement (in counterparts or otherwise) by facsimile transmission or other electronic transmission (including in the form of a .PDF file) shall be sufficient to bind the parties to the terms and conditions of this Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement effective upon the Effective Date set forth above. Each person signing this agreement hereby represents that he or she is authorized by the organization on whose behalf he or she is signing to enter into the Agreement.

Green Mountain Care Board

Signature: _____

Name: _____

Date _____

Title: _____

Authorized User

Signature: Gordon Jensen

Name: Gordon Jensen

Date: Nov 22, 2017

Title: Sr. Associate Dean of Research

Organization: Larner College of Medicine at UVM

Department of VT Health Access

Signature: _____

Name: _____

Date: _____

Title: _____

Principal Investigator (if different than Authorized User)

Signature: CMMacLean

Name: Charles MacLean

Date: 11.14.17

Title: Associate Dean of Primary Care

Organization: Larner College of Medicine at UVM

Attachment 2

Data Governance Policies and Procedures
Regarding the Vermont Health Care Uniform Reporting and Evaluation System at the University of Vermont
Updated November, 2017

The Vermont Health Care Uniform Reporting and Evaluation System (VHCURES) will be used by researchers at the University of Vermont (UVM), to conduct health services research that is non-proprietary, serves the public interest, and is applicable to large populations. All research will be conducted in a manner consistent with the Green Mountain Care Board (GMCB) Data Protection and Disclosure Guide, including future updates to the Guide adopted by the GMCB. Researcher groups at UVM will comprise faculty, staff, and students working in teams and under the rules and regulations of the Institutional Review Board (IRB), a UVM committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans.

UVM agrees to:

1. Define the "**Authorized User**" and designate an individual signatory in writing. The Authorized User is the licensee ultimately responsible for the approved use of the VHCURES health care claims data sets. The individual signing the VHCURES Data Use Agreement (Agreement) on behalf of the Authorized User must be a person having the authority to bind the organization to the terms of the Agreement and all Attachments, including this Attachment A. Upon termination of the Agreement, the signatory must certify to the GMCB that all VHCURES data has been destroyed or returned.

Authorized User:	The University of Vermont
Signatory:	Gordon Jensen
Title:	Professor of Medicine, Senior Associate Dean for Research
Street/PO Address:	89 Beaumont Ave
City/State/ZIP:	Burlington, VT 05401
Phone Number:	802-656-2156
Email Address:	gordon.jensen@uvm.edu
Fax Number:	802-656-8577

2. Designate an individual "**Project Director**" in writing. The Project Director is the person with oversight of all VHCURES research projects on behalf of the Authorized User. The Project Director is responsible for:
   a) Ensuring compliance with all aspects of this document and the Agreement;
   b) Requesting the VHCURES limited use extract for UVM;
   c) Ensuring that the approved VHCURES limited use extracts released by the GMCB are properly routed to the Data Custodian/Security Director (see item 3) for loading and managing;
   d) Reviewing UVM researcher requests for individual projects proposing to use VHCURES;

e) Ensuring that the Data Custodian and Security Director provide approved UVM research projects with appropriate access to VHCURES data;
f) Notifying the GMCB in advance of any new project or research question UVM proposes to address. Such notification shall include completing the attached *Scope of Work Form* as well as any necessary IRB documentation;
g) Maintaining a log or other record of all VHCURES data requests and releases, including confirmation of the completion of any research projects and the return or destruction of data as required by this document and Agreement;
h) Maintaining a log or other record of all UVM VHCURES researchers, their signed Individual User Affidavits, and start and end dates of approved access;
i) Filing Individual User Affidavits, data tracking reports, certificates of destruction, and other documents as required under the Agreement with the GMCB;
j) The notification, logging, and communication requirements in sections f, g, h, and i, may be met by the posting of documents to the *UVM-VHCURES Commons* secure website that is accessible to the GMCB. This online document repository was created and has been in use for the purpose of tracking data access and use activity related to the Agreement;
k) Ensuring compliance with all GMCB restrictions, limitations, and conditions of use associated with all VHCURES data releases.

The GMCB or its agents may, upon request, review the records required to be kept under this section. UVM will continue to provide access to the *UVM-VHCURES Commons* secure website for the GMCB or its designee to review the logs and records at any time and to download documents as needed by the GMCB for the duration of the Agreement.

Project Director:	Charles MacLean
Title:	Professor of Medicine
Street/PO Address:	89 Beaumont Ave
City/State/ZIP:	Burlington, VT 05401
Phone Number:	802-656-8250
Email Address:	charles.maclean@uvm.edu
Fax Number:	802-656-4576

3. Identify the individual "**Data Custodian and Security Director**" in writing. The Data Custodian and Security Director is an individual designated by the Authorized Institutional User and is responsible for the physical security of the VHCURES data. The Data Custodian and Security Director will maintain a secure computer server for storing the VHCURES limited use extract as well as the individual data releases for approved individual research projects. The server environment will contain statistical software so that all analyses can be performed behind a secure firewall. The Data Custodian and Security Director, with support from the Project Director, is responsible for ensuring that no VHCURES data are removed from the secure server environment until the data are to be destroyed or returned pursuant to the Agreement.

Data Custodian and Security Director:	Jill Jemison
Title:	Director, College of Medicine Information Technology
Street/PO Address:	89 Beaumont Ave

City/State/ZIP:	Burlington, VT 05401
Phone Number:	802-656-0076
Email Address:	Jill.Jemison@uvm.edu
Fax Number:	802-656-4576

4. Designate a **VHCURES Data Stewardship Committee** (VDSC). Members of the VDSC will be designated by the Authorized User and will include UVM researchers engaged in research projects utilizing the VHCURES data. In addition, the VDSC will include the Authorized User, the Project Director, the Data Custodian and Security Director or their designees. The VDSC will meet periodically and will support the Project Director by reviewing UVM researcher requests for research projects using VHCURES data (requests are submitted using the attached Scope of Work Form) and ensuring compliance with all aspects of the Agreement. Agendas and minutes for each of the meetings of the VDSC will be made available to the GMCB via an online reporting repository.

5. Require all employees, contractors and agents of any kind to comply with all applicable provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and other federal and Vermont laws with respect to the data shared under the Agreement. UVM agrees to require and maintain an Individual User Affidavit for each researcher or other individual granted access to this data, and such agreements will be filed with the GMCB. Nothing in this paragraph authorizes sharing data provided under the Agreement with any other entity for any purpose.

6. Maintain all VHCURES and other GMCB data in a secure environment and not copy, reproduce, or transmit data except as necessary to fulfill the purpose of the original request. All copies of data of any type, including any modifications or additions to data from any source that contains information regarding individuals, are subject to the provisions of this document and Agreement in the same manner as the original data. The ability to access or maintain data under this Agreement shall not under any circumstances transfer from UVM to any other institution or entity

7. Not disclose, in published results of studies as authorized by the Agreement, any data obtained under this Agreement in a manner that could identify an individual to any other entity in published results of studies as authorized by the Agreement, nor attempt to infer or deduce the identity of any individual, nor claim to have identified or deduced the identity of any individual. To ensure the confidentiality of individuals, the minimum size of any population cohort described in any reporting must be more than 10. If there are 10 or fewer individuals, the report should say, "10 or less" or "<11". Data shall not be disclosed in a manner that could be used to ascertain the identity of individuals included in a minimum-sized cohort. All data suppression rules outlined in the Agreement, Individual User Affidavit, and Data Protection and Disclosure Guide will be followed.

8. Shall immediately report any unauthorized disclosures of Medicare data that may result in a potential breach of personally identifiable information and/or personal health information to the Centers for Medicare and Medicaid Services (CMS) Action Desk by telephone at (410)

786-2580 and by e-mail notification at cms_it_service_desk@cms.hhs.gov within one hour and to cooperate fully in the federal security incident process.

9. Immediately report to the GMCB following notification of the CMS Action Desk as noted above in Section 8 pertaining to Medicare data, any use or disclosure of data including commercial, Medicaid, and Medicare not provided for by the Agreement. The Data Breach Incident Report shall be filed with the GMCB within 24 hours of the discovery of such unauthorized use or disclosure of data. In the event that such unauthorized use or disclosure does occur, UVM will devise a mitigation plan in consultation with appropriate GMCB staff and take all reasonable steps to implement this plan.

10. Refrain from providing any data obtained under the Agreement to any party without the permission of the GMCB.

11. Confirm that and explain how any original or derivative data initially provided to VHCURES from CMS, including Medicare data, will be used exclusively for performing research that is directed by and at least partially funded by the State. A section is included in the *Scope of Work Form* to specify the funding for each specific project.

12. Provide to the GMCB a data tracking report, in a format produced by UVM and approved by the GMCB, that is updated quarterly and lists specific research studies for which VHCURES data are being used, individual data users, and physical location of the data.

13. Obtain IRB approval for research projects for which data are being used pursuant to the Agreement prior to the release of data to the UVM researchers. IRB documentation must be filed or made available to the GMCB via the *UVM-VHCURES Commons* secure website for the duration of the Agreement.

14. Provide copies of all draft reports such as presentation or articles generated from VHCURES data to the GMCB for review prior to publication. The GMCB will review all materials intended for public dissemination to help ensure compliance with conditions of use as describe in the Agreement. The GMCB staff will provide acknowledgement of receipt of materials and a review within a timeframe mutually agreed upon by UVM and the GMCB.

15. Provide the GMCB with an electronic copy of the final versions of all reports or publications associated with the project within 30 days of submission for public dissemination as requested by the GMCB. The GMCB reserves the right to distribute and otherwise use the final report and associated documents as it wishes, in sum or in part. In general, no copyright, trademark, or similar intellectual property right or obligation may limit or interfere with the GMCB's unrestricted right to distribute or otherwise use the final report and associated documents as it wishes, in sum or in part. GMCB will honor the copyright ownership of scientific journal publishers and the embargo dates required by publishers holding copyrights to work that is pending publication. The GMCB will give appropriate credit to UVM researchers in any redistribution of UVM work.

16. Guarantee that matching of VHCURES data to other data sets will only be permitted if and to the extent it is approved by the GMCB.

17. Destroy or return all data obtained under the Agreement when it is no longer needed for the purpose for which it was obtained. Nothing in the Agreement authorizes UVM to maintain data beyond the time period reasonably needed to complete the purpose of the request as deemed reasonable by GMCB. UVM agrees to require all employees, contractors, or agents of any kind to comply with this provision. Projects will be designated as ACTIVE (ongoing analysis), RETURNED (analysis complete but data are in the "returned" state and not accessible to the researcher), or CLOSED (data destroyed). This will be recorded in the data tracking report described in item 12 above. The UVM Data Custodian and Security Director will maintain a secure data location for storage of "returned" data. The status of "returned" data shall be included in the quarterly data tracking report noted under section 11 in this Policy and Procedures document. In the event that reanalysis is required, authorization to re-access the data will be required from the GMCB.

18. Confirm that destruction or return of data shall be documented by submission of a Certificate of Data Destruction as provided by GMCB. UVM agrees to destroy or return all data in the event that the Agreement is terminated.

19. Agree that GMCB makes no warranty concerning the accuracy of the data provided.

20. Represents that it is authorized to bind to the terms of the Agreement all individuals who may have access to the data maintained by UVM.

21. Acknowledge that the terms of this Attachment 2 *Agency's Data Governance and Protection Policies and Procedures* may be modified or amended in writing provided that any such modification or amendment is mutually agreed to by both parties.

22. The following six pages comprises a sample *Scope of Work Form* described in section 2.f above:

Data Governance Policies and Procedures
Regarding Research Utilizing the Vermont Health Care Uniform Reporting and Evaluation System at the University of Vermont

Scope of Work Form
With italicized instructions for investigators

1. Project Title:

2. Principal Investigator Name and Title:

3. Scope of Work:

Provide a brief description of the research study for which the researcher is requesting use of VHCURES data under the Data Governance Policies and Procedures. Include a description of the research questions being addressed with particular attention to the objectives and potential significance of the study. Note that UVM is required to provide the GMCB with quarterly updates on the list of research studies for which the data shared per this agreement is being used including identification of individual data users and location of the VHCURES data being accessed by authorized individual users on the project team

4. Intended use of VHCURES data for Population Health or Health Policy:

Describe how the intended use of VHCURES data examines health care access, utilization, expenditures and system performance for the Vermont population through a systematic investigation designed to develop or contribute to generalizable knowledge.

5. Intended use of VHCURES: data marketing clause

Address intended use of VHCURES per CMS guidelines: "CMS will not support research that will lead to the creation of a product or tool that the researcher intends to market. Any tool developed using CMS data is to be made available to the entire public, without charge. CMS will review the source of funding to determine if the requestor is independent of the funding organization. For example, CMS has historically denied data requests from requestors wanting to evaluate the impact of prescription drugs if a pharmaceutical company finances the study." See http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/Researchers.html

6. Estimated Project Timeline:

Provide a brief description of the estimated timeline for the research study supported by this agreement. Include in this description the estimated time frame needed to destroy or return the data in accordance with the agreement. Any extensions to the effective end date or the time frame for destruction or return of the data will require a signed addendum to the original agreement that is approved by the GMCB.

7. Authorized Representative:

The data use agreement requires UVM to designate in writing a "Project Director" responsible for transmitting all data requests and maintaining a log or other record of all data requested and received pursuant to this Agreement, including confirmation of the completion of any projects and the return or destruction of data as required by this agreement. In addition, the Project Director is responsible for ensuring all study personnel have read the GMCB Data Protection and Disclosure Guide and have signed an Individual User Affidavit that will be filed with the GMCB.

Project Director: Charles Maclean, MD

Title: Professor of Medicine

8. Description of Data Being Requested

Provide a detailed description of the file types and the granularity of data elements requested per this data sharing agreement. In your description, include information on the specific data elements being requested for this research study in addition to those indicated on the Data Granularity Table below.

Table of Files Types – *CHECK WHICH FILES ARE REQUESTED*

File Type	Commercial Insurers	Medicaid	Medicare
Medical Eligibility			
Medical Claims			
Pharmacy Eligibility			Not applicable
Pharmacy Claims			Not applicable
Medical Eligibility- 5% Medicare National Sample	Not applicable	Not applicable	
Medical Claims- 5% Medicare National Sample	Not applicable	Not applicable	
Medicare Part D Event- VT Residents	Not applicable	Not applicable	
Medicare Part D Event- 5% National Sample	Not applicable	Not applicable	
Medicare MEDPAR	Not applicable	Not applicable	

Data Granularity Table

Data Element(s)	Reason needed to achieve the proposed research objective
Member, Enrollee, Beneficiary, Patient Information	
Full Date of Birth	
Single Year Age (including >89)	
Town/City	
5-digit ZIP Code	
Date of Service (medical claims)	
Date Prescription Filled	
Provider Information	
Service Provider Name	
Service Provider NPI	
Billing Provider Name	
Billing Provider NPI	
Prescribing Physician Name	
Commercial Insurer Information	
Insurer ID/Name	
Charge/Allowed Amount	
Paid Amount	

9. Description of Secure Data Storage Procedures:

All study data, including derived datasets, must be stored and analyzed on the College of Medicine Technology Services ("COMTS") supported secure Med72 server. For information on how to obtain access to the Med72 secure server contact: Jill Jemison, COMTS

In order to support the security requirements for our most sensitive data, The University of Vermont College of Medicine has deployed SEDRC, a Secure Environment for Data and Research Computing. SEDRC systems are configured based on one of three security tiers (confidential, restricted, and prohibited) as defined by UVM information security policies. The VHCURES data is housed within this environment on Prohibited systems, the most secure. Prohibited systems require that data is stored on encrypted volumes, transferred over encrypted connections, and cannot leave the environment unless approved by the VHCURES Data Stewardship Committee. Three systems have been deployed to support VHCURES: An analytics server running statistical software, a data storage server running Microsoft SQL, and a secure file transfer server running Accellion kiteworks. In order to gain access to these systems approval from the VHCURES Data Stewardship Committee is required.

10. Investigators

Provide a list of study personnel for the proposed research study, including all individuals that will be accessing data elements in this data sharing agreement. Describe the role, responsibilities and expertise of each individual. At a minimum, each research study must include individuals with expertise in the proposed content area, statistical methods, and health care claims analysis. In addition, a single study principal investigator (PI) must be assigned. The PI will be responsible for working with the Project Director to ensure all aspects of the proposed study are in compliance with the requirements outlined in the agreement. All study personnel must read and agree to adhere by the GMCB Data Protection and Disclosure Guide and sign an Individual User Affidavit that will be filed with the GMCB.

Example:

Principal Investigator: Valerie Harder, MHS, PhD
Role and responsibility: Overall project direction; supervision of co-investigators
Expertise: Health care claims analysis; statistical methodology

Co-investigator: Richard Wasserman, MD
Role and responsibility: Collaboration on study design, analysis, and reporting
Expertise: Health care claims analysis; pediatric population health

Research assistant data analyst: John Doe
Role and responsibility: Data cleaning and analysis
Expertise: Health care claims analysis; data cleaning

11. Funding Sources

Detail the existing and planned funding sources for this work. If grant-funded, identify the source(s) of the grant funds. If the work entails data by or through CMS data kept in VHCURES, please explain how the work is at least partially funded by the state of Vermont.

State of Vermont

Does the proposed work use CMS data? Yes

If yes, please explain how the work is at least partially funded by the State of Vermont.

Note that for all UVM projects regardless of project funding source, State funds come to the College of Medicine each year to support a variety of activities. We have dedicated a portion of these funds to support VHCURES and other CMS-based projects. This support is specified in four ways: 1) 3% of the College of Medicine Senior Associate Dean for Research's salary to support her/his role as Authorized Institutional User; 2) 3% of the College of Medicine Director of Technology Services' salary to support her/his role as Data Custodian and Security Director; 3) 3% of the salary of the UVM COM faculty member designated as the Project Director; and 4) 10% of the College of Medicine Technology Services Systems Administrator designated to receive and perform initial processing on the VHCURES/CMS data.

For specific projects

For specific projects there may be other ways in which the work is partially funded by the state.
Example from VCHIP project:
"The proposed work will examine the delivery of health services in primary and specialty settings in Vermont practices. This work will be carried out by a team from the Vermont Child Health Improvement Program which is funded by the State of Vermont to analyze and improve the health of Vermonters."

12. Materials for public dissemination

Provide a detailed description of the types of materials that will be generated in order to report the results of the study. Types of materials may include, but not be limited to, oral presentations, white papers, conferences, posters, peer-reviewed manuscripts, etc. All resulting materials for public dissemination from the study must meet the data suppression requirements outlined in the agreement. All study materials intended for public dissemination must be reviewed by the GMCB to ensure compliance with data suppression rules prior to release or publication.
For example: "We anticipate presenting findings at a national conference such as Academy Health" or "We anticipate publishing a peer-reviewed manuscript in a pediatric journal." "Materials will include summary tables of results, figures, and text descriptions of findings."

Check all that apply:

✓ Conference presentation
Description: We anticipate presenting our findings at a national conference such as the

✓ Manuscript
Description: We anticipate publishing a manuscript based on our findings and will target the following publications:

☐ Other
Description:

The UNIVERSITY of VERMONT
Committees on Human Subjects
Serving the University of Vermont
and the UVM Medical Center

RESEARCH PROTECTIONS OFFICE
213 Waterman Building
85 South Prospect Street
Burlington, Vermont 05405
(802)656-5040 ph
www.uvm.edu/irb/

Memorandum
(Continuing Review)

TO:	Charles MacLean, MD
FROM:	Sarah Wright, Research Review Analyst
DATE:	10-Oct-2017
SUBJECT:	CHRMS: 16-155 Vermont Health Care Uniform Reporting and Evaluation System (VHCURES) Data Repository

Attached is a signed assurance form which certifies this application has been reviewed and approved. Also attached is the IRB's list of key personnel for this protocol. Below is a list of the approved consent process(es):

- Waiver of informed consent and, if applicable, approval for a waiver of individual authorization for disclosure of protected health information.

As the Principal Investigator of this approved protocol you have specific responsibilities. Please refer to the Research Manual, Section 9. Submission of Materials After Initial Approval is Obtained and Section 10. Investigator Responsibilities to review these responsibilities and obtain further guidance.

Personnel Roster At Time of Continuing Review Approval

TO: Charles MacLean, MD

FROM: IRB Staff

DATE: 10-Oct-2017

SUBJECT: Key Personnel Listing

CHRMS: 16-155

Vermont Health Care Uniform Reporting and Evaluation System (VHCURES) Data Repository

Below is the IRB's list of key personnel at the time of continuing review approval. To update the roster, you must submit a Request for Change in Key Personnel form.

Thank you for contacting the Committee.

Name

Jemison, Jill Kirsch

MacLean, Charles D

The University of Vermont Committees on Human Research

Biological Specimens/Data Repository Protocol

A. Committee on Human Research, General Clinical Research Center &/or Vermont Cancer Center

DATE STAMP	Shaded Sections	PROTOCOL NUMBER
	For Committee on Human Research Use Only	

1. REPOSITORY NAME/PROJECT

Vermont Health Care Uniform Reporting and Evaluation System (VHCURES) Data Repository

2. INVESTIGATOR INFORMATION

*Principal Investigator (PI):	Charles MacLean			Degree:	MD
Dept.	Primary Care	Phone	6-8250	E-Mail	charles.maclean@uvm.edu
Campus/Office Address:	89 Beaumont Ave			Fax	6-4576
PI's Dept. Chair(s)					

Is PI UVM Faculty?* Yes [X] No [ ] Is PI UVM Medical Center Employee?* Yes [X] No [ ]

Is PI UVM Employee only? Yes [ ] No [x]

Is the PI a Fellow [ ] Resident [ ] Or Student? [ ] If yes to any, complete #11 below.

Check graduate status if applicable: [ ] Graduate [ ] Undergraduate

***NOTE:** Under normal circumstances only UVM or UVM Medical Center individuals can be PI. If you are not affiliated with either UVM nor UVM Medical Center, you must stop here and contact the RPO office for additional guidance.

DO YOU WANT TO APPOINT PRIMARY CONTACT OTHER THAN PI?: Yes [ ] No [X]

*Investigators wishing to appoint a contact for **all** IRB communications should complete the contact information requested below. **Primary contacts are considered "key personnel" and must complete required human subjects training.***

Contact Full Name		Email*	
Department /Address		Fax Number	
Campus Phone Number/ Pager			

3. PURPOSE OF REPOSITORY: *The information must include: (1) objectives or aims, (2) a brief but specific description of the procedure(s) involving the human subjects, their specimens and/or data, and (3) what types of research is hoped to be done utilizing the repository. Do not exceed one single-spaced 8 ½ X 11" page.*

Medical claims analysis is a method increasingly used by health care researchers to better understand health care utilization, treatment choices, and medical expenditures. The purpose of the repository is to create yearly datasets of Vermont patients from Vermont's all-payer claims dataset, the Vermont Healthcare Claims Uniform Reporting and Evaluation System (VHCURES) to be used by researchers at the University of Vermont.

The University of Vermont (UVM) has a data use agreement (DUA) with the Green Mountain Care Board (GMCB) to obtain data from VHCURES. The GMCB is a quasi-governmental organization charged with regulating and evaluating Vermont's health care system. The GMCB is also responsible for Vermont's all-payer claims datasets, which include medical and pharmacy claims data, as well as insurance eligibility data for more than 90% of Vermonters. These data allow for population-based analyses of the health care system, and provide a comprehensive, longitudinal look at the changing healthcare landscape in Vermont. The agreement between UVM and the GMCB helps to fulfill the mission of the GMCB to support health services research

by supplying datasets to researchers who have the competency and expertise to conduct proposed studies that will ultimately answer important healthcare questions about costs and utilization.

The DUA between UVM and GMCB specifies an administrative structure at UVM which includes an "Authorized User" (Russ Tracey), a "Project Director" (Charles MacLean), a "Data Security Director" (Jill Jemison), and a "Data Stewardship Committee". The DUA also specifies procedures for proposing research questions that are acceptable to the GMCB based on their federal and state responsibilities.

UVM plans to retain copies of VHCURES datasets managed by the GMCB that have been created on a perioidic basis since 2008. UVM will add to the repository each time a new dataset is released by the GMCB. These datasets will be made available to researchers at the university who complete the approval process outlined by the DUA with the GMCB. Briefly, the DUA requires researchers to obtain UVM IRB approval, to have their proposal reviewed by a UVM VHCURES Stewardship Committee by submitting a "Scope of Work" document detailing the planned use of the data, to review UVM and GMCB data security requirements and sign required user affidavits, and to have their proposal reviewed by the GMCB data governance counsel or its designees.

Researchers at UVM using VHCURES via this repository will be overseen by the Data Stewardship Committee and by the Project Director identified in the DUA, who is named as the Principal Investigator of this IRB protocol. Data acquisition (receiving data from the GMCB) and data distribution (creating datasets for use by specific UVM researchers) will be tracked. Analytic products created from analyses using VHCURES data will also be monitored to ensure that such products (e.g., figures, tables) meet GMCB rules for data security and suppression of small cell sizes. Data supplied to researchers from the repository will be restricted to only the requested and proposal-approved variables.

The DUA also requires that once individual research projects are completed, the data extracts used in the analyses be either returned to the state or destroyed.

The lifecycle of each project using the repository will be tracked on a secure website to be accessed by the Project Director, Data Security Director, and GMCB to review the progress of researchers and track project open and close dates.

4. TYPE OF REVIEW

a. Which type of IRB review you are requesting? **Full** [ ] **Expedited** [X] Complete category.

Your research may be expeditable if the research activities (1) present **no more than minimal risk** to human subjects, and (2) **involve only procedures listed in one or more of the following categories**: (CHECK THE CATEGORY(IES) THAT APPLY.

[ ] (1) **Clinical studies of drugs and medical devices only when condition (a) or (b) is met.**
(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).
(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

[ ] (2) **Collection of blood samples** by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week: or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

[ ] (3) Prospective **collection of biological specimens** for research purposes by noninvasive means.

[ ] (4) **Collection of data through noninvasive procedures** (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

[X] (5) Research involving **materials** (data, documents, records, or specimens) that have been collected, or will be **collected solely for nonresearch purposes** (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 .CFR 46.101 (b)(4). This listing refers only to research that is not exempt.)

[ ] (6) **Collection of data from voice, video, digital, or image recordings** made for research purposes.

[ ] (7) **Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.** (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3)).

b. Is this research developed and written by industry? Yes [ ] No [X]

(drug or device company – industry sponsored)

c. Is this research developed and written by a UVM/UVM Medical Center researcher? Yes [ ] No [X]

(investigator initiated)

d. Does the research involve the study of cancer or is it cancer-related? Yes [ ] No [X]

If yes, this research is also subject to a separate review by the Vermont Cancer Center. Click here, Protocol Review Committee , for the requirements.

e. Does the research involve the use of any General Clinical Research Center (GCRC) facilities or resources?

Yes [ ] No [X]

If yes, research is subject to a separate review by the GCRC. Click here, Scientific Advisory Committee, for the requirements.

5. OTHER KEY PERSONNEL – Complete Section 10.

6. Fletcher Allen Health Care Compliance Coverage Analysis and Billing Plan Approval

j. Will this study involve any UVM Medical Center patients (including data and or specimens) or any equipment, facilities, supplies or personnel of UVM Medical Center, whether standard of care or protocol-driven, such as laboratory, pharmacy, imaging, EKGs, or other diagnostic or therapeutic items or staff?

Yes [ ] No [X]

If the answer to any part of the above question is Yes, the UVM Medical Center Compliance Office will need to approve a billing plan prior to the release of IRB approval. For more information, please reference "Research Billing Compliance" on the Fletcher Allen Health Care website. For additional questions, call Denise Quint in the Fletcher Allen Integrity and Compliance department at 847-9482.

7. SOURCE OF SUPPORT, CONTRACT/AGREEMENTS, AND FEES

a. Source of Funding - *Check all that apply.*

[X] **UVM/UVM Medical Center Department** Specify Dept(s): **College of Medicine**

[ ] **UVM Grant processed by SPA Pre-Award Services** – Non-Industry

(e.g. NIH, DOD, cooperative groups, other state or local ,private foundations, etc.)

Name of Funding Agency

InfoEd Proposal #

Funding Agency Grant Number

Is this a Program Project grant? [ ] Yes [ ] No

If yes, list PI on the Program Project grant

What is the status of the grant? [ ] Awarded [ ] Pending [ ] Just in Time Request

If the award is pending or Just-In-Time, do you intend to begin research activities prior to obtaining the funding? [ ] Yes [ ] No

If yes, the consent form, if applicable, cannot include the funding agency. Once the funding has been received, you must submit an amendment to provide the final awarded grant document and to update the consent form with the funding agency's name.

Attach corresponding grant proposal.

[ ] **Industry Supported Research processed through UVM SPA Pre-Award Services**

InfoEd Proposal #

Name of Company

[ ] **Industry Supported Research processed through UVM Medical Center Office of Clinical Trials Research**

Name of Company

What support is the Company providing?

[ ] Monetary reimbursement to UVM Medical Center for patient enrollment.

[ ] Test Drug*

[ ] Test Device*

[ ] Other List:

*If the Company is providing only the drug or device, it is not subject to IRB fees.

b. Contracts/Agreements - *Contracts are required for any industry supported protocol.*

If this is an industry supported protocol, what is the status of the contract/agreement?

☐ Complete ☐ Pending

If complete attach a copy.

If it is pending, which institution is assisting you with its completion?

☐ UVM Medical Center - Office of Clinical Trials Research or ☐ UVM - SPA Pre-Award Services

c. Protocols Subject to IRB Fees

"The University's Institutional Review Boards (IRBs) charge fees for initial and annual continuing review for all UVM Medical Center studies sponsored by pharmaceutical firms and other for-profit entities, and to review protocols for outside organizations. Fees are not charged for University or UVM Medical Center federal, non-profit foundation, or departmentally-funded studies. The fee schedule is reviewed each year by the IRB and is subject to change."

Does the protocol meet the above criteria? ☐ Yes ☒ No

If yes, provide the Company's billing information below.

Name	
Contact Person Name for the Invoice	
Contact Person E-mail address	
Street Address	
City, State, Zip	

8. SPECIMEN/DATA REPOSITORY INFORMATION

a. Location/Security/Contents

i. Identify the Repository Manager (provide name, email, fax and telephone)

Data Custodian and Security Director
Jill Jemison
Jill.Jemison@uvm.edu
Phone: 6-0076
Fax: 6-4576

ii. How and where will specimens/information be stored?

VHCURES data will be stored on two servers maintained by the College of Medicine Technology Services department. One server (VHCURES Repository Server) will house the data repository. Another server (Med72) will house data extracts, which are smaller subsets of the larger datasets used to answer specific, researcher-driven questions created for researchers using VHCURES data.

Data from the GMCB will be transmitted to the Repository Manager/Data Custodian and Security Director and staff, and placed on the VHCURES Repository Server. After review by the UVM VHCURES Data Stewardship Committee and the GMCB, the Repository Manager/Data Custodian and Security Director or designated staff will work with researchers to extract smaller subsets of data for analysis and place that data on Med72 for researchers to access.

iii. Repository will include: (check all that apply)

☐ Existing Specimens
☐ Prospectively Collected Specimens
☒ Existing Private Information
☐ Prospectively Collected Private Information

iv. Who will have access to subject identities?

Neither the Repository Manager/Data Custodian and Security Director, PI, or individual UVM researchers have access to a master list that would link the coded VHCURES patient ID to a person's name, social security number, or insurance id number. The data will arrive with only the assigned coded VHCURES patient ID.

v. How will specimens/information stored by the repository be labeled? (For example, a unique identifier assigned by the repository)

The information is labeled by coded VHCURES patient ID that is applied by the insurer before it

reaches the vendor, Onpoint Health Data.

vi. What are the security measures in place. (e.g., password protected computer (desktop or laptop), data on protected server, locked freezers, locked file cabinets)

The security supporting the both the VHCURES Repository server and the Med72 server, has been implemented through both written polices and technical measures. Policy documents include a signed Memorandum of Understanding (MOU) between the College of Medicine Technology Services department and specific research groups that clearly describes acceptable use and delineation of responsibilities. In addition, all employees of the University of Vermont must follow all UVM policies, including the Information Security policy (http://www.uvm.edu/policies/cit/infosecurity.pdf).

To support these policies and the security requirements of the data sets this system has been implemented with multiple technical measures. Network security has been implemented by placing the system in an isolated private network, which is protected by an enterprise grade firewall. In addition, access to the system is only allowed through a secure Virtual Private Network, which requires multi-factor authentication. Data security has been implemented by requiring that any data stored on the system be isolated using file/folder and share level permissions and is encrypted on disk.

Data on server housing the complete repository is only accessible by the Repository Manager/Data Custodian and Security Director and her administration team and security engineer. This group will be responsible for both loading datasets onto the VHCURES Repository server and for creating data extracts for researchers and moving those extracts to Med72.

UVM Researchers access Med72 using two-factor authentication. The first factor is the college of medicine username/password that has been given specific permissions to the server. The second factor is a token assigned by the College of Medicine server to the user for the duration of the current session. The user retrieves the token using a hard token or a mobile app, and must enter the token to verify the log in process and gain access to the server space. This token cannot be reused in future sessions by the user.

Once in the server space, the user has access to statistical software to conduct analyses and will not remove the data from the protected space. Only summary tables/statistical output tables are approved for export.

vii. Describe the specimens & related information (blood, CSF, urine, etc. (fresh, sterile, formalin-fixed etc.) names, diagnoses)

viii. If collection of information only, describe information to be collected.

Data include medical and pharmacy claims, and eligibility information of more than 90% of Vermonters. This includes 90% of privately insured Vermonters, and 100% of Vermonters covered by Medicaid or Medicare. Such data includes, but is not limited to, healthcare cost and utilization information such as dates of service received, current procedural codes, diagnosis codes, costs, providers, provider locations, etc. It also includes information about covered lives including dates of birth, dates of death, insurance coverage information, ages, and zip codes.

ix. Duration that specimens/information will be kept. (if indefinite explain)

This repository will be kept indefinitely. By maintaining all years of VHCURES datasets as they are released we can maintain a rich longitudinal dataset that will be most valuable to UVM researchers and strengthen their ability to more confidently answer research questions about healthcare by looking at trends over time, confirming the impact of interventions or quality improvement projects on future patients.

x. Will you conduct genetic testing as part of the repository activity? Yes ☐ No ☒
If no, skip to section xi. If yes, respond to each of the following questions.

i. Do your studies involve the analysis of genes known to be implicated in the disorder(s), syndrome(s), or conditions(s) you are studying? Yes ☐ No ☐

If yes, what genes will you study?

ii. Alternatively, do your studies involve finding the gene(s) that may cause the condition, or genetic markers that co-segregate with this condition? Yes ☐ No ☐

iii. Will you be collecting information from affected individuals only? Yes ☐ No ☐
If yes, will you also collect information from family members of affected individuals (whether affected or unaffected)? Yes ☐ No ☐

iv. Are there affective treatments for the diseases/syndromes that you are studying? Yes ☐ No ☐
Are the disease/syndromes treatable or curable? Yes ☐ No ☐
What are the ages at onset?

v. Is it possible that your testing will provide evidence of previously undiagnosed or unrecognized illness, or susceptibility to illness? Yes ☐ No ☐
If no, skip to next question.
If yes, will you provide subjects with this information? Yes ☐ No ☐
Will this information be provided by trained genetic counselors? Yes ☐ No ☐
If no, explain who will provide this information and what training they have had

vi. NOTE: This research activity invokes the Genetic Information Nondiscrimination Act (GINA) because the protocol collects, stores and/or analyzes genetic materials. GINA requires that you provide information to subjects regarding protection of their genetic information. You may find template language for your consent form in our IRB consent form template (under risks).

xi. Will you create or store cell lines as part of the repository activity? Yes ☐ No ☒

b. Collection Procedures

i. How will the cases be identified and collected? (e.g. medical records, hospital computer, pathology, directly from subjects) (obtaining specimens or private information prospectively almost always requires informed consent and (as applicable) HIPAA authorization from the subject)

Medical claims data are submitted by insurance companies to Onpoint Health Data, which manages the submission of data and creates datasets for the GMCB. Onpoint maintains VHCURES and creates limited use datasets for research purposes which UVM will receive as part of the DUA with the GMCB.

ii. List sites (hospitals, etc) collecting the specimens/information.

All insurers offering services to Vermonters are required by state mandate to contribute to VHCURES. This includes Medicaid and Medicare, but does not include insurers covering state employees, military personnel, and their children, or insurers with fewer than 200 members.

iii. For specimens collected in the course of routine medical care, what procedures are in place to ensure that adequate material is available for patient care and that patient care will not be compromised as a result of specimen banking?

The medical claim itself, as a record of care, does not impact the patient care at the visit and patient care is not compromised as a result of keeping this administrative record.

iv. For specimens collected in non-clinical areas, explain procedures to be followed?

The collection of medical claims is overseen by Onpoint. Insurers register with Onpoint and use a secure portal online to submit claims. Before submitting data to Onpoint, insurers use a federally recommended hashing algorithm to encrypt patient-identifiable data including, but not limited to, social security number, patient name, member identification code, subscriber number, and subscriber name, and assigns a unique identifier to each covered life. Data is then submitted through the online portal where it is cleaned and screened by

Onpoint and added to VHCURES. UVM then receives a copy of VHCURES from Onpoint as specified by the DUA between the GMCB and UVM. The data deposits will be tracked using the Data Acquisition Tracking Form.

v. Explain how the specimens/information acquisition will be tracked. Attach gate-keeping forms used for this purpose. See example of database fields at end of form.

Each year that we add to the repository we will make a record of the date of the receipt and of general attributes of the dataset for that year. Any adjustments or corrections to the dataset as recommended by the GMCB or its vendors will also be noted.

vi. Explain how you will confirm that informed consent has been obtained for storage of the specimens/data.

We will not be able to confirm that patients have read and received information about HIPPA or the Privacy Rule. We are able to use de-identified data, this repository poses no more than a minimal risk to the privacy of individuals, we cannot practically obtain consent, and the research proposed hinges on use of protected health information.

c. Access to Repository

i. Who will have access to the specimens/information? (check all that apply)

- [X] Only key personnel listed on this repository form
- [X] Only researchers affiliated with UVM/UVM Medical Center
- [ ] Researchers at other educational or non-profit research institutions *(list in 7.c.viii.)*
- [ ] Researchers affiliated with industry or for-profit organizations *(list in 7.c.viii.)*
- [X] Others (specify)

NOTE: UVM investigators sending data or specimens outside of the institution should contact the UVM Office of Technology Commercialization to determine if a Material Transfer Agreement or any other agreement defining the respective institutional responsibilities is warranted.

The GMCB will have access to summary data, tables, and figures for review as outlined by our DUA.

ii. Explain how requests to use the specimens/information will be reviewed by the PI/study personnel:

Researcher requests to use the repository will be reviewed by the UVM VHCURES Data Stewardship Committee to ensure that the requests comply with the aims of the GMCB for the release of VHCURES data (see 'Scope of Work' form, attached). Concurrently, requests to use the repository will also be reviewed by the IRB as new project proposals (full, expedited, or non-human subjects, as appropriate). Once the project is reviewed by the UVM VHCURES Stewardship Committee, it may be forwarded to the GMCB and its designees for review as 'with IRB approval' or 'pending IRB approval'. The GMCB then has the opportunity to review each project's Scope of Work and any IRB documents.

Data extracts for researchers will not be created for the researcher until they have received approval from the UVM VHCURES Stewardship Committee, the UVM IRB, and the GMCB. The researcher must also sign a data use affidavit (per the DUA with the GMCB) and complete a security orientation to using VHCURES data via Med72. Once these steps are completed, the researcher can obtain a data extract from the Repository Manager/Data Custodian and Security Director or her designated staff.

iii. Explain how you will track distribution (if any) of the specimens/information and attach any agreements or gate-keeping forms used for this purpose.

We will track the distribution and use of datasets using a Data Distribution Tracking Form that includes the project title, the project PI, other project personnel, the project's IRB number, the date of IRB approval, the date of approval by the UVM VHCURES Stewardship Committee, the data of approval by the GMCB, the date they signed the user affidavit, the date of the first data extraction, the date their proposed project's conclusion, and if there are any final reports from the project.
We will also track the data extracts made for each researcher (DBA Extract Tracking Form).

iv. Explain how secondary distribution of specimens/information will be controlled?

Secondary distribution will not be allowed.

v. Confirm that you will require proof of IRB approval prior to release of specimen/information to a secondary person.

Confirm [X]

vi. What mechanisms are in place to assure that future uses of subject specimens/information are consistent with the informed consent obtained at the time of initial specimen/information collection?

Not applicable

vii. List receiving sites not under UVM/UVM Medical Center IRB jurisdiction below

none

d. Identification of Specimens/Information *(check one i, ii ,iii, or iv)*

[ ] i. With identifiers (e.g., names, patient numbers) attached. If you checked this box, explain what identifiers will be attached:

Explain why it is necessary to retain these identifiers:

How long will identifiers be kept? If indefinitely, explain why this is necessary. (for example you intend to follow the course of treatment or disease, or you want to contact or re-contact subjects)

Under no circumstances should subjects be contacted without explicit prior approval by the IRB (make a definitive statement to this effect).

Will users, not listed as key personnel, be allowed access to specimens/data with identifiers? If yes, explain why this is necessary and how you will protect the use of this information.

[ ] ii. With a repository or study code, linked to identifiers on a master list.

Where will the master list be kept?

Who will have access to the master list? Specify whether they will have access to specimens/information with identifiers or only to coded specimens/information with no access to identifiers.

[X] iii. With a unique code that is not linked to any other code or identifiers

Explain the procedure by which the specimens/information is de-linked from subject identities. (e.g. when is the de-linking performed, what entity performs the de-linking, and what identifying information is removed and how)

Before submitting data to Onpoint, insurers use a federally recommended hashing algorithm to encrypt patient-identifiable data including, but not limited to, social security number, patient name, member identification code, subscriber number, and subscriber name. A unique id is assigned at this time.

[ ] iv. With a study code for which the repository does not have access to the master list (attach data use agreement with other entity specifying no access to identifiers)

9. HUMAN SUBJECT INFORMATION

a. Type and Number of Specimens/Subject Data (check all that apply):

Subjects	# of Subjects[1]	Subjects	# of Subjects[1]
[X] Male		[X] Pregnant Women	
[X] Female		[ ] Fetuses	
[X] Students		[ ] Prisoners	

[ ]	Employees		[X]	Diminished Capacity	
[X]	Normal Volunteers		[X]	Non-English Speaking	
[X]	Adults [Age Range: 18-26]		[X]	Wards of State	
[X]	Minors [Age Range:0-17]				
[ ]	Specific Disorder				

Explain

[ ] Other Potentially Vulnerable

Do the subjects have rare diseases or are there characteristics of individuals or groups that would allow ready identification? Comment below.

It is possible that diseases or disorders with low prevalence could allow researchers to identify patients. This issue of identification will be addressed in those protocols as appropriate to protect the identity of patients by possibly requiring them to use aggregated data, to reduce the granularity of their request (such as increasing the unit of analysis by using services occurring in a month rather than by specific day, for example) or take other measure.

[1] If you wish to receive approval for open-ended or unlimited numbers, please explain why this is necessary below.

This repository is based on all medical claims for Vermonters. It is not possible to know the exact number of claims we will receive for each category. We can make estimates based on population, but they will not take into account migration into and out of the state.

b. Will subjects be compensated? Yes [ ] No [X]

If yes, explain which subjects in your pool will be compensated and how. *(e.g. subjects with or without disease/condition, monetary or other)*

If you are providing monetary compensation, explain how you will be obtaining the subjects' social security number? (e.g., on paper, verbally) *(UVM and UVM Medical Center require subject social security numbers for payment.)*

10. CONSENT/AUTHORIZATION

a. Are you obtaining complete written consent and HIPAA authorization? (includes all elements) *If yes, skip to section c.* [ ] Yes [X] No

b. Are you requesting a Waiver of Informed Consent and HIPAA authorization? [X] Yes [ ] No

This request means that you will not be obtaining verbal nor written consent. If yes, complete the form *Request for a Waiver of Informed Consent/Authorization/Documentation Section I and skip to section 10 in this form.*

c. Consent Process/Required Elements

i. Once a prospective subject is identified, who initiates the informed consent discussion and answers questions presented by the subject or the subject's family? *(provide names of all consenters)*

ii. Where (in what setting) is the informed consent process initiated? How much time is the subject given to decide?

iii. Is the principal investigator present for the initial and subsequent informed consent discussions with the subject?

iv. What other method of documentation is used to record the informed consent process, in addition to the executed consent form? *See an example of documentation of the informed consent **process** on our website.*

v. What policies and procedures are in place to protect privacy and confidentiality? Comment here and in consent form.

vi. Will subjects be able to withdraw their specimen/information from the repository? If yes, explain the procedure for withdrawal and what happens to the specimen/information below and in the consent form.

vii. Will you retain any specimens/information that could reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability or reputation? (for example, use of illegal drugs, underage drinking, child or elder abuse, sexual behavior, disease condition, genetic test results, etc) If yes, identify the information and explain why it could put the subject at risk below and in the consent form.

viii. Is it possible that you might be obliged or compelled (for example, in response to a subpoena for evidence) to disclose specimens/information that could be linked with an individual or group? If yes, explain these circumstances below and in the consent form. If you have a federal Certificate of Confidentiality, then state so here and in consent form.

ix. Will results of this research or future tests be communicated to the subjects? Comment below the information that will be provided and the process to evaluate the risk vs benefits associated with the return of individual research results. Include in the consent form.

x. Are there plans to re-contact subjects to request additional samples/information? Explain below and explain in consent form. Subject should have the option to participate but not to be re-contacted.

11. PERSONNEL ROSTER

All personnel with access to subjects or their data are required to have completed human subjects protection training within the last three years. To check completions go to http://www.uvm.edu/~irb/education/TutorialCOMPLETION.htm.

Note: A UVM NetID is required to complete the training. *To request a UVM NetID, complete and submit the "Request for UVM Net ID for Required Training" form. Training completion for all key personnel is not required prior to submission of this form, however it is required prior to final protocol approval. If you have someone in need of a UVM NetID to complete this requirement, complete the column "Date of Request for UVM NetID" in lieu of the Date of Tutorial Completion. Attach additional sheets if necessary.

	Personnel Name	**Email Address**	**Date of Tutorial Completion** (within last three years)	**Date of Request for UVM NetID** (only necessary if you can't complete training for lack of a UVM NetID)
1.	Charles MacLean	Charles.MacLean@uvm.edu	3/21/14	
2.	Jill Jemison	Jill.Jemison@uvm.edu	9/24/15	
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

12. AGREEMENTS

PRINCIPAL INVESTIGATOR

As Principal Investigator of this study, I assure the Committees on Human Research that the following statements are true:

The information that is provided in this form is correct. I will seek and obtain prior written approval from the IRB for any modifications in the proposal, including changes in procedures, co-investigators, etc. All of the members of the research team have completed the applicable institutional credentialing processes required to conduct this research. I will promptly forward any reportable adverse events and unanticipated problems to subjects or others that may occur in the course of this study. I will report in writing any significant new findings that develop during the course of this study that may affect the risks and benefits to participation. I will not begin my research until I have received written notification of IRB approval. I will comply with all IRB requests to report on the status of the study. I certify that the research team will collect only information essential to the study in accord with the HIPAA Minimum Necessary Standard and I will limit, to the greatest extent possible, access to the information. I assure that the information I obtain as part of this research including PHI will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law or for authorized oversight of the research project. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entities, I will seek prior IRB approval. I will maintain records of this research according to applicable guidelines. If I am seeking IRB approval for a sponsored project, I hereby certify that the application that I have submitted to my funding agency accurately and completely reflects what is contained in this application. Agreement allows invoicing and collection of IRB review fees.

x _____ 9/25/2015

Original Signature of PI | Date

FACULTY SPONSOR (if applicable and referenced on page one, section 2, of this form)

Advisor's Name: _____ Telephone Number: _____

Department/Address: _____ E-mail: _____

Date of Human Subjects Tutorial Completion _____

Policy Statement from the Research Manual: *"As the responsible investigator, the faculty sponsor or course instructor is required to complete the Human Subjects in Research tutorial. Protocol approvals will not be released until that requirement has been met." Completion of this requirement is every three years. The training can be found at* http://www.uvm.edu/irb/tutorial/index.html

Is there is a thesis or dissertation committee reviewing this research? Yes ☐ No ☐

If yes, date of approval: _____

As the faculty sponsor for this protocol, I certify that the student will conduct this research under my supervision and guidance. I further certify that I will assume final responsibility for the conduct of this protocol in accordance with all University of Vermont and Federal Regulations relating to human research as outlined above and in the Human Subjects Research Manual.

x _____ _____

Original Signature of Faculty Sponsor | Date

_____

Printed Name

13. Attachments This checklist is optional.

	Item	If applicable Version #	Dated
☐	Complete copy of grant proposal with budget (if applicable)		

	Consent Form/HIPAA Authorization		
	Child Assent Form (if applicable)		
	Request for Waiver of Consent/HIPAA Authorization		
	Agreements with Other Collaborators		
	Surveys/Questionnaires		
	Other:		

Example of Acquisition Tracking

Date of Collection	Subject Name and or code	Description	Informed Consent Obtained?	Future Research requires consent?	Future Research for (? Disease Only?)	Future Research for any conditions?	Can be contacted for future research.	Date of Withdrawal of Specimen and or Information
8/4/01	1002	Liver tissue	yes	no	yes	yes	no	10/09/05

Example of Distribution Tracking

Subject Name and or code	Recipient IRB Approval or exemption?	Specimen sent to (name)	Location	Date Sent	What was sent?

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

GMCB USE ONLY
Vermont Healthcare Claims Uniform Reporting & Evaluation System (VHCURES)
Data Use Agreement #
State Agency or Instrumentality ( )
Commercial Data ( )
Medicare Data ( )
Medicaid Data ( )
Non-State Entity ( )
Commercial Data ( )
Medicaid Data ( )
GMCB Signature/Date: _____

DUA Expiration Date:

I, Charles MacLean, affiliated with the agency, organization, or company titled

University of Vermont College of Medicine affirm as follows:

1. I have been designated by the Authorized User or Principal Investigator identified on the Green Mountain Care Board (GMCB) Data Use Agreement (DUA) #_____ as an Individual User who will use or have access to the information disclosed by GMCB under the DUA.

2. [ ] I agree that I have read the DUA and agree to adhere to the provisions set forth in the DUA addressing the protection of confidential, restricted, personally identifiable and personal health information as required under Vermont law and regulations and by the federal Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) as the absolute baseline for data and information protection.

3. [ ] I have read the DUA and agree to adhere to the requirements addressing the actions I will take in the event that there is a suspected or actual breach that could result in the unauthorized disclosure of confidential, restricted, personally identifiable and personal health information.

4. [ ] I have read the DUA and agree to adhere to limiting the use and disclosure of the data and information provided by GMCB under this DUA to the uses and disclosures approved by GMCB and if applicable, as approved by the Department of Vermont Health Access (DVHA) for Medicaid data and by the Centers for Medicare & Medicaid Services (CMS) for Medicare data.

5. [ ] I have read the DUA understand that I may be subject to civil, criminal and monetary penalties for violations use and disclosure guidelines as stipulated in the DUA authorized by GMCB and that GMCB and/or DVHA and/or CMS may prosecute to the fullest extent of applicable state and federal laws.

6. [ ] I have read the DUA and agree to abide by all the provisions included in the DUA issued by GMCB including those provisions stipulated in the DUA between GMCB and CMS and those stipulated in the Memorandum of Understanding between GMCB and DVHA.

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

7. [ ] I understand that to the extent any of the above terms of this affidavit conflict with the DUA that the terms of the DUA take precedent and that this Affidavit in no way abrogates or changes the DUA.

8 . I affirm under penalty of perjury that all of my statements above are true and correct.

11.14.17
Date

Individual User Signature

Charles MacLean
Name (Printed)

Associate Dean for Primary Care
Title

University of Vermont College of Medicine
Organization/Employer

802 656-8250
Phone Number

charles.maclean@uvm.edu
Email Address

AUTHORIZED USER/PRINCIPAL INVESTIGATOR ONLY:

As the Authorized User and/or the Principal Investigator as defined in the GMCB DUA #_____ and as signatory on the Data Use Agreement, I have approved the access to and usage of the data for this above-identified Individual User as approved by GMCB and, if applicable.

Authorized User and/or Principal Investigator Signature

Gordon Jensen
Name (Printed)

University of Vermont College of Medicine
Organization/Employer

Nov. 22, 2017
Date

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

GMCB USE ONLY
Vermont Healthcare Claims Uniform Reporting & Evaluation System (VHCURES)
Data Use Agreement #
State Agency or Instrumentality ( )
Commercial Data ( )
Medicare Data ( )
Medicaid Data ( )
Non-State Entity ( )
Commercial Data ( )
Medicaid Data ( )
GMCB Signature/Date: _____

DUA Expiration Date:

I, Stephen L. Goldman, affiliated with the agency, organization, or company titled University of Vermont Larner College of Medicine affirm as follows:

1. I have been designated by the Authorized User or Principal Investigator identified on the Green Mountain Care Board (GMCB) Data Use Agreement (DUA) #_____ as an Individual User who will use or have access to the information disclosed by GMCB under the DUA.

2. [✓ SLG] I agree that I have read the DUA and agree to adhere to the provisions set forth in the DUA addressing the protection of confidential, restricted, personally identifiable and personal health information as required under Vermont law and regulations and by the federal Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) as the absolute baseline for data and information protection.

3. [✓ SLG] I have read the DUA and agree to adhere to the requirements addressing the actions I will take in the event that there is a suspected or actual breach that could result in the unauthorized disclosure of confidential, restricted, personally identifiable and personal health information.

4. [✓ SLG] I have read the DUA and agree to adhere to limiting the use and disclosure of the data and information provided by GMCB under this DUA to the uses and disclosures approved by GMCB and if applicable, as approved by the Department of Vermont Health Access (DVHA) for Medicaid data and by the Centers for Medicare & Medicaid Services (CMS) for Medicare data.

5. [✓ SLG] I have read the DUA understand that I may be subject to civil, criminal and monetary penalties for violations use and disclosure guidelines as stipulated in the DUA authorized by GMCB and that GMCB and/or DVHA and/or CMS may prosecute to the fullest extent of applicable state and federal laws.

6. [✓ SLG] I have read the DUA and agree to abide by all the provisions included in the DUA issued by GMCB including those provisions stipulated in the DUA between GMCB and CMS and those stipulated in the Memorandum of Understanding between GMCB and DVHA.

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

DUA

7. [✓] I understand that to the extent any of the above terms of this affidavit conflict with the DUA that the terms of the DUA take precedent and that this Affidavit in no way abrogates or changes the DUA.

8 . I affirm under penalty of perjury that all of my statements above are true and correct.

11/17/2017
Date

Individual User Signature

Stephen L. Goldman
Name (Printed)

Manager, Database + Programming Services
Title

University of Vermont Larner College of Medicine
Organization/Employer

802- 656-9770
Phone Number

Stephen.goldman@med.uvm.edu
Email Address

AUTHORIZED USER/PRINCIPAL INVESTIGATOR ONLY:

As the Authorized User and/or the Principal Investigator as defined in the GMCB DUA #_____ and as signatory on the Data Use Agreement, I have approved the access to and usage of the data for this above-identified Individual User as approved by GMCB and, if applicable.

Authorized User and/or Principal Investigator Signature

CHARLES MACLEAN
Name (Printed)

UVM
Organization/Employer

11.20.17
Date

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

GMCB USE ONLY
Vermont Healthcare Claims Uniform Reporting & Evaluation System (VHCURES)
Data Use Agreement #
State Agency or Instrumentality ( )
Commercial Data ( )
Medicare Data ( )
Medicaid Data ( )
Non-State Entity ( )
Commercial Data ( )
Medicaid Data ( )
GMCB Signature/Date: _____

DUA Expiration Date:

I, Jill Jemison, affiliated with the agency, organization, or company titled University of Vermont Larner College of Medicine affirm as follows:

1. I have been designated by the Authorized User or Principal Investigator identified on the Green Mountain Care Board (GMCB) Data Use Agreement (DUA) #_____ as an Individual User who will use or have access to the information disclosed by GMCB under the DUA.

2. [✓] I agree that I have read the DUA and agree to adhere to the provisions set forth in the DUA addressing the protection of confidential, restricted, personally identifiable and personal health information as required under Vermont law and regulations and by the federal Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) as the absolute baseline for data and information protection.

3. [✓] I have read the DUA and agree to adhere to the requirements addressing the actions I will take in the event that there is a suspected or actual breach that could result in the unauthorized disclosure of confidential, restricted, personally identifiable and personal health information.

4. [✓] I have read the DUA and agree to adhere to limiting the use and disclosure of the data and information provided by GMCB under this DUA to the uses and disclosures approved by GMCB and if applicable, as approved by the Department of Vermont Health Access (DVHA) for Medicaid data and by the Centers for Medicare & Medicaid Services (CMS) for Medicare data.

5. [✓] I have read the DUA understand that I may be subject to civil, criminal and monetary penalties for violations use and disclosure guidelines as stipulated in the DUA authorized by GMCB and that GMCB and/or DVHA and/or CMS may prosecute to the fullest extent of applicable state and federal laws.

6. [✓] I have read the DUA and agree to abide by all the provisions included in the DUA issued by GMCB including those provisions stipulated in the DUA between GMCB and CMS and those stipulated in the Memorandum of Understanding between GMCB and DVHA.

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

7. [✓] I understand that to the extent any of the above terms of this affidavit conflict with the DUA that the terms of the DUA take precedent and that this Affidavit in no way abrogates or changes the DUA.

8 . I affirm under penalty of perjury that all of my statements above are true and correct.

11/17/17
Date

Individual User Signature

Jill Jemison
Name (Printed)

CIO, Health Sciences
Title

University of Vermont Larner College of Medicine
Organization/Employer

802-656-0076
Phone Number

jill.jemison@med.uvm.edu
Email Address

AUTHORIZED USER/PRINCIPAL INVESTIGATOR ONLY:

As the Authorized User and/or the Principal Investigator as defined in the GMCB DUA #_____ and as signatory on the Data Use Agreement, I have approved the access to and usage of the data for this above-identified Individual User as approved by GMCB and, if applicable.

Authorized User and/or Principal Investigator Signature

Charles MacLean
Name (Printed)

UVM
Organization/Employer

11.20.17
Date

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

GMCB USE ONLY
Vermont Healthcare Claims Uniform Reporting & Evaluation System (VHCURES)
Data Use Agreement #
State Agency or Instrumentality ( )
Commercial Data ( )
Medicare Data ( )
Medicaid Data ( )
Non-State Entity ( )
Commercial Data ( )
Medicaid Data ( )
GMCB Signature/Date: _____

DUA Expiration Date:

I, ALMER RIVERA, affiliated with the agency, organization, or company titled UNIVERSITY OF VERMONT affirm as follows:

1. I have been designated by the Authorized User or Principal Investigator identified on the Green Mountain Care Board (GMCB) Data Use Agreement (DUA) #_____ as an Individual User who will use or have access to the information disclosed by GMCB under the DUA.

2. [✓] I agree that I have read the DUA and agree to adhere to the provisions set forth in the DUA addressing the protection of confidential, restricted, personally identifiable and personal health information as required under Vermont law and regulations and by the federal Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) as the absolute baseline for data and information protection.

3. [✓] I have read the DUA and agree to adhere to the requirements addressing the actions I will take in the event that there is a suspected or actual breach that could result in the unauthorized disclosure of confidential, restricted, personally identifiable and personal health information.

4. [✓] I have read the DUA and agree to adhere to limiting the use and disclosure of the data and information provided by GMCB under this DUA to the uses and disclosures approved by GMCB and if applicable, as approved by the Department of Vermont Health Access (DVHA) for Medicaid data and by the Centers for Medicare & Medicaid Services (CMS) for Medicare data.

5. [✓] I have read the DUA understand that I may be subject to civil, criminal and monetary penalties for violations use and disclosure guidelines as stipulated in the DUA authorized by GMCB and that GMCB and/or DVHA and/or CMS may prosecute to the fullest extent of applicable state and federal laws.

6. [✓] I have read the DUA and agree to abide by all the provisions included in the DUA issued by GMCB including those provisions stipulated in the DUA between GMCB and CMS and those stipulated in the Memorandum of Understanding between GMCB and DVHA.

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

7. [✓] I understand that to the extent any of the above terms of this affidavit conflict with the DUA that the terms of the DUA take precedent and that this Affidavit in no way abrogates or changes the DUA.

8. I affirm under penalty of perjury that all of my statements above are true and correct.

NOV. 17, 2017
Date

Individual User Signature

ALMER RIVERA
Name (Printed)

DATABASE ADMINISTRATOR
Title

UNIVERSITY OF VERMONT
Organization/Employer

(802) 656-5300
Phone Number

ALMER.RIVERA@MED.UVM.EDU
Email Address

AUTHORIZED USER/PRINCIPAL INVESTIGATOR ONLY:

As the Authorized User and/or the Principal Investigator as defined in the GMCB DUA #_____ and as signatory on the Data Use Agreement, I have approved the access to and usage of the data for this above-identified Individual User as approved by GMCB and, if applicable.

Authorized User and/or Principal Investigator Signature

Charles MacLean
Name (Printed)

UVM
Organization/Employer

11.20.17
Date

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

GMCB USE ONLY
Vermont Healthcare Claims Uniform Reporting & Evaluation System (VHCURES)
Data Use Agreement #
State Agency or Instrumentality ( )
Commercial Data ( )
Medicare Data ( )
Medicaid Data ( )
Non-State Entity ( )
Commercial Data ( )
Medicaid Data ( )
GMCB Signature/Date: _____
DUA Expiration Date:

I, Lindsay Van Leir, affiliated with the agency, organization, or company titled University of Vermont. affirm as follows:

1. I have been designated by the Authorized User or Principal Investigator identified on the Green Mountain Care Board (GMCB) Data Use Agreement (DUA) #_____ as an Individual User who will use or have access to the information disclosed by GMCB under the DUA.

2. [✓] I agree that I have read the DUA and agree to adhere to the provisions set forth in the DUA addressing the protection of confidential, restricted, personally identifiable and personal health information as required under Vermont law and regulations and by the federal Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) as the absolute baseline for data and information protection.

3. [✓] I have read the DUA and agree to adhere to the requirements addressing the actions I will take in the event that there is a suspected or actual breach that could result in the unauthorized disclosure of confidential, restricted, personally identifiable and personal health information.

4. [✓] I have read the DUA and agree to adhere to limiting the use and disclosure of the data and information provided by GMCB under this DUA to the uses and disclosures approved by GMCB and if applicable, as approved by the Department of Vermont Health Access (DVHA) for Medicaid data and by the Centers for Medicare & Medicaid Services (CMS) for Medicare data.

5. [✓] I have read the DUA understand that I may be subject to civil, criminal and monetary penalties for violations use and disclosure guidelines as stipulated in the DUA authorized by GMCB and that GMCB and/or DVHA and/or CMS may prosecute to the fullest extent of applicable state and federal laws.

6. [✓] I have read the DUA and agree to abide by all the provisions included in the DUA issued by GMCB including those provisions stipulated in the DUA between GMCB and CMS and those stipulated in the Memorandum of Understanding between GMCB and DVHA.

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

7. [✓] I understand that to the extent any of the above terms of this affidavit conflict with the DUA that the terms of the DUA take precedent and that this Affidavit in no way abrogates or changes the DUA.

8. I affirm under penalty of perjury that all of my statements above are true and correct.

11/14/17
Date

Individual User Signature

Lindsay VanLeir
Name (Printed)

Research Specialist
Title

VCHIP, University of Vermont
Organization/Employer

802-656-9879
Phone Number

lindsay.van-leir@med.uvm.edu
Email Address

AUTHORIZED USER/PRINCIPAL INVESTIGATOR ONLY:

As the Authorized User and/or the Principal Investigator as defined in the GMCB DUA #_____ and as signatory on the Data Use Agreement, I have approved the access to and usage of the data for this above-identified Individual User as approved by GMCB and, if applicable.

Authorized User and/or Principal Investigator Signature

Charles MacLean
Name (Printed)

University of Vermont Medical Center
Organization/Employer

11.28.17
Date

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

GMCB USE ONLY
Vermont Healthcare Claims Uniform Reporting & Evaluation System (VHCURES)
Data Use Agreement #
State Agency or Instrumentality ( )
Commercial Data ( )
Medicare Data ( )
Medicaid Data ( )
Non-State Entity ( )
Commercial Data ( )
Medicaid Data ( )
GMCB Signature/Date: _____
DUA Expiration Date:

I, Richard Wasserman affiliated with the agency, organization, or company titled University of Vermont affirm as follows:

1. I have been designated by the Authorized User or Principal Investigator identified on the Green Mountain Care Board (GMCB) Data Use Agreement (DUA) #_____ as an Individual User who will use or have access to the information disclosed by GMCB under the DUA.

2. [X] I agree that I have read the DUA and agree to adhere to the provisions set forth in the DUA addressing the protection of confidential, restricted, personally identifiable and personal health information as required under Vermont law and regulations and by the federal Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) as the absolute baseline for data and information protection.

3. [X] I have read the DUA and agree to adhere to the requirements addressing the actions I will take in the event that there is a suspected or actual breach that could result in the unauthorized disclosure of confidential, restricted, personally identifiable and personal health information.

4. [X] I have read the DUA and agree to adhere to limiting the use and disclosure of the data and information provided by GMCB under this DUA to the uses and disclosures approved by GMCB and if applicable, as approved by the Department of Vermont Health Access (DVHA) for Medicaid data and by the Centers for Medicare & Medicaid Services (CMS) for Medicare data.

5. [X] I have read the DUA understand that I may be subject to civil, criminal and monetary penalties for violations use and disclosure guidelines as stipulated in the DUA authorized by GMCB and that GMCB and/or DVHA and/or CMS may prosecute to the fullest extent of applicable state and federal laws.

6. [X] I have read the DUA and agree to abide by all the provisions included in the DUA issued by GMCB including those provisions stipulated in the DUA between GMCB and CMS and those stipulated in the Memorandum of Understanding between GMCB and DVHA.

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

7. [X] I understand that to the extent any of the above terms of this affidavit conflict with the DUA that the terms of the DUA take precedent and that this Affidavit in no way abrogates or changes the DUA.

8 . I affirm under penalty of perjury that all of my statements above are true and correct.

11-17-2017
Date

Individual User Signature

Richard Wasserman
Name (Printed)

Professor of Pediatrics,
Title

University of Vermont College of Medicine
Organization/Employer

802-656-3046
Phone Number

richard.wasserman@med.uvm.edu
Email Address

AUTHORIZED USER/PRINCIPAL INVESTIGATOR ONLY:

As the Authorized User and/or the Principal Investigator as defined in the GMCB DUA # _____ and as signatory on the Data Use Agreement, I have approved the access to and usage of the data for this above-identified Individual User as approved by GMCB and, if applicable.

Authorized User and/or Principal Investigator Signature

Charles MacLean
Name (Printed)

University of Vermont Medical Center.
Organization/Employer

11.28.17
Date

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

GMCB USE ONLY
Vermont Healthcare Claims Uniform Reporting & Evaluation System (VHCURES)
Data Use Agreement #
State Agency or Instrumentality ( )
Commercial Data ( )
Medicare Data ( )
Medicaid Data ( )
Non-State Entity ( )
Commercial Data ( )
Medicaid Data ( )
GMCB Signature/Date: _____

DUA Expiration Date:

I, Valerie Harder, affiliated with the agency, organization, or company titled University of Vermont affirm as follows:

1. I have been designated by the Authorized User or Principal Investigator identified on the Green Mountain Care Board (GMCB) Data Use Agreement (DUA) # _____ as an Individual User who will use or have access to the information disclosed by GMCB under the DUA.

2. [✓] I agree that I have read the DUA and agree to adhere to the provisions set forth in the DUA addressing the protection of confidential, restricted, personally identifiable and personal health information as required under Vermont law and regulations and by the federal Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) as the absolute baseline for data and information protection.

3. [✓] I have read the DUA and agree to adhere to the requirements addressing the actions I will take in the event that there is a suspected or actual breach that could result in the unauthorized disclosure of confidential, restricted, personally identifiable and personal health information.

4. [✓] I have read the DUA and agree to adhere to limiting the use and disclosure of the data and information provided by GMCB under this DUA to the uses and disclosures approved by GMCB and if applicable, as approved by the Department of Vermont Health Access (DVHA) for Medicaid data and by the Centers for Medicare & Medicaid Services (CMS) for Medicare data.

5. [✓] I have read the DUA understand that I may be subject to civil, criminal and monetary penalties for violations use and disclosure guidelines as stipulated in the DUA authorized by GMCB and that GMCB and/or DVHA and/or CMS may prosecute to the fullest extent of applicable state and federal laws.

6. [✓] I have read the DUA and agree to abide by all the provisions included in the DUA issued by GMCB including those provisions stipulated in the DUA between GMCB and CMS and those stipulated in the Memorandum of Understanding between GMCB and DVHA.

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

7. [✓] I understand that to the extent any of the above terms of this affidavit conflict with the DUA that the terms of the DUA take precedent and that this Affidavit in no way abrogates or changes the DUA.

8. I affirm under penalty of perjury that all of my statements above are true and correct.

11/14/2017
Date

Individual User Signature

Valerie S. Harder
Name (Printed)

Associate Professor
Title

University of Vermont
Organization/Employer

802-656-2652
Phone Number

valerie.harder@med.uvm.edu
Email Address

AUTHORIZED USER/PRINCIPAL INVESTIGATOR ONLY:

As the Authorized User and/or the Principal Investigator as defined in the GMCB DUA #_____ and as signatory on the Data Use Agreement, I have approved the access to and usage of the data for this above-identified Individual User as approved by GMCB and, if applicable.

Authorized User and/or Principal Investigator Signature

Charles MacLean
Name (Printed)

University of Vermont Medical Center
Organization/Employer

11.28.17
Date

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

GMCB USE ONLY
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Data Use Agreement #
State Agency or Instrumentality ( )
Commercial Data ( )
Medicare Data ( )
Medicaid Data ( )
Non-State Entity ( )
Commercial Data ( )
Medicaid Data ( )
GMCB Signature/Date: _____
DUA Expiration Date:

I, Matthew Hollander affiliated with the agency, organization, or company titled University of Vermont affirm as follows:

1. I have been designated by the Authorized User or Principal Investigator identified on the Green Mountain Care Board (GMCB) Data Use Agreement (DUA) # _____ as an Individual User who will use or have access to the information disclosed by GMCB under the DUA.

2. [✓] I agree that I have read the DUA and agree to adhere to the provisions set forth in the DUA addressing the protection of confidential, restricted, personally identifiable and personal health information as required under Vermont law and regulations and by the federal Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) as the absolute baseline for data and information protection.

3. [✓] I have read the DUA and agree to adhere to the requirements addressing the actions I will take in the event that there is a suspected or actual breach that could result in the unauthorized disclosure of confidential, restricted, personally identifiable and personal health information.

4. [✓] I have read the DUA and agree to adhere to limiting the use and disclosure of the data and information provided by GMCB under this DUA to the uses and disclosures approved by GMCB and if applicable, as approved by the Department of Vermont Health Access (DVHA) for Medicaid data and by the Centers for Medicare & Medicaid Services (CMS) for Medicare data.

5. [✓] I have read the DUA understand that I may be subject to civil, criminal and monetary penalties for violations use and disclosure guidelines as stipulated in the DUA authorized by GMCB and that GMCB and/or DVHA and/or CMS may prosecute to the fullest extent of applicable state and federal laws.

6. [✓] I have read the DUA and agree to abide by all the provisions included in the DUA issued by GMCB including those provisions stipulated in the DUA between GMCB and CMS and those stipulated in the Memorandum of Understanding between GMCB and DVHA.

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

7. [ ] I understand that to the extent any of the above terms of this affidavit conflict with the DUA that the terms of the DUA take precedent and that this Affidavit in no way abrogates or changes the DUA.

8 . I affirm under penalty of perjury that all of my statements above are true and correct.

28 NOV 2017
Date

Individual User Signature

Matthew Hollander
Name (Printed)

Assitant Professor, Pediatrics
Title

University of Vermont College of Medicine
Organization/Employer

802-656-9197
Phone Number

matthew.hollander@uvm.edu
Email Address

AUTHORIZED USER/PRINCIPAL INVESTIGATOR ONLY:

As the Authorized User and/or the Principal Investigator as defined in the GMCB DUA #_____ and as signatory on the Data Use Agreement, I have approved the access to and usage of the data for this above-identified Individual User as approved by GMCB and, if applicable.

Authorized User and/or Principal Investigator Signature

Charles MacLean
Name (Printed)

University of Vermont Medical Center
Organization/Employer

11.28.17
Date

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

GMCB USE ONLY
Vermont Healthcare Claims Uniform Reporting & Evaluation System (VHCURES)
Data Use Agreement #
State Agency or Instrumentality ( )
Commercial Data ( )
Medicare Data ( )
Medicaid Data ( )
Non-State Entity ( )
Commercial Data ( )
Medicaid Data ( )
GMCB Signature/Date: _____
DUA Expiration Date:

I, Judy Shaw, affiliated with the agency, organization, or company titled University of Vermont affirm as follows:

1. I have been designated by the Authorized User or Principal Investigator identified on the Green Mountain Care Board (GMCB) Data Use Agreement (DUA) #_____ as an Individual User who will use or have access to the information disclosed by GMCB under the DUA.

2. [✓] I agree that I have read the DUA and agree to adhere to the provisions set forth in the DUA addressing the protection of confidential, restricted, personally identifiable and personal health information as required under Vermont law and regulations and by the federal Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) as the absolute baseline for data and information protection.

3. [✓] I have read the DUA and agree to adhere to the requirements addressing the actions I will take in the event that there is a suspected or actual breach that could result in the unauthorized disclosure of confidential, restricted, personally identifiable and personal health information.

4. [✓] I have read the DUA and agree to adhere to limiting the use and disclosure of the data and information provided by GMCB under this DUA to the uses and disclosures approved by GMCB and if applicable, as approved by the Department of Vermont Health Access (DVHA) for Medicaid data and by the Centers for Medicare & Medicaid Services (CMS) for Medicare data.

5. [✓] I have read the DUA understand that I may be subject to civil, criminal and monetary penalties for violations use and disclosure guidelines as stipulated in the DUA authorized by GMCB and that GMCB and/or DVHA and/or CMS may prosecute to the fullest extent of applicable state and federal laws.

6. [✓] I have read the DUA and agree to abide by all the provisions included in the DUA issued by GMCB including those provisions stipulated in the DUA between GMCB and CMS and those stipulated in the Memorandum of Understanding between GMCB and DVHA.

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

7. [✓] I understand that to the extent any of the above terms of this affidavit conflict with the DUA that the terms of the DUA take precedent and that this Affidavit in no way abrogates or changes the DUA.

8 . I affirm under penalty of perjury that all of my statements above are true and correct.

11/21/17
Date

Judy Shaw
Individual User Signature

Judy Shaw
Name (Printed)

Executive Director
Title

VCHIP, University of Vermont
Organization/Employer

802-656-8319
Phone Number

judith.shaw@med.uvm.edu
Email Address

AUTHORIZED USER/PRINCIPAL INVESTIGATOR ONLY:

As the Authorized User and/or the Principal Investigator as defined in the GMCB DUA #_____ and as signatory on the Data Use Agreement, I have approved the access to and usage of the data for this above-identified Individual User as approved by GMCB and, if applicable.

Authorized User and/or Principal Investigator Signature

Charles MacLean
Name (Printed)

University of Vermont Medical Center.
Organization/Employer

11.28.17
Date

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3901

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

GMCB USE ONLY
Vermont Healthcare Claims Uniform Reporting & Evaluation System (VHCURES)
Data Use Agreement #
State Agency or Instrumentality ( )
Commercial Data ( )
Medicare Data ( )
Medicaid Data ( )
Non-State Entity ( )
Commercial Data ( )
Medicaid Data ( )
GMCB Signature/Date:
DUA Expiration Date:

I, Keith Robinson, affiliated with the agency, organization, or company titled University of Vermont affirm as follows:

1. I have been designated by the Authorized User or Principal Investigator identified on the Green Mountain Care Board (GMCB) Data Use Agreement (DUA) #_____ as an Individual User who will use or have access to the information disclosed by GMCB under the DUA.

2. [✓] I agree that I have read the DUA and agree to adhere to the provisions set forth in the DUA addressing the protection of confidential, restricted, personally identifiable and personal health information as required under Vermont law and regulations and by the federal Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) as the absolute baseline for data and information protection.

3. [✓] I have read the DUA and agree to adhere to the requirements addressing the actions I will take in the event that there is a suspected or actual breach that could result in the unauthorized disclosure of confidential, restricted, personally identifiable and personal health information.

4. [✓] I have read the DUA and agree to adhere to limiting the use and disclosure of the data and information provided by GMCB under this DUA to the uses and disclosures approved by GMCB and if applicable, as approved by the Department of Vermont Health Access (DVHA) for Medicaid data and by the Centers for Medicare & Medicaid Services (CMS) for Medicare data.

5. [✓] I have read the DUA understand that I may be subject to civil, criminal and monetary penalties for violations use and disclosure guidelines as stipulated in the DUA authorized by GMCB and that GMCB and/or DVHA and/or CMS may prosecute to the fullest extent of applicable state and federal laws.

6. [✓] I have read the DUA and agree to abide by all the provisions included in the DUA issued by GMCB including those provisions stipulated in the DUA between GMCB and CMS and those stipulated in the Memorandum of Understanding between GMCB and DVHA.

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

7. [✓] I understand that to the extent any of the above terms of this affidavit conflict with the DUA that the terms of the DUA take precedent and that this Affidavit in no way abrogates or changes the DUA.

8. I affirm under penalty of perjury that all of my statements above are true and correct.

11/21/17
Date

Individual User Signature

Keith Robinson
Name (Printed)

MD, Director of Quality at UVM Children's Hospital.
Title

University of Vermont Medical Center.
Organization/Employer

802-847-0689
Phone Number

keith.robinson@uvmhealth.org
Email Address

AUTHORIZED USER/PRINCIPAL INVESTIGATOR ONLY:

As the Authorized User and/or the Principal Investigator as defined in the GMCB DUA #_____ and as signatory on the Data Use Agreement, I have approved the access to and usage of the data for this above-identified Individual User as approved by GMCB and, if applicable.

Authorized User and/or Principal Investigator Signature

Charles MacLean.
Name (Printed)

University of Vermont Medical Center
Organization/Employer

11.28.17
Date

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

GMCB USE ONLY
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Data Use Agreement #
State Agency or Instrumentality ( )
Commercial Data ( )
Medicare Data ( )
Medicaid Data ( )
Non-State Entity ( )
Commercial Data ( )
Medicaid Data ( )
GMCB Signature/Date: _____

DUA Expiration Date:

I, Susan E.V. Richardson, affiliated with the agency, organization, or company titled University of Vermont affirm as follows:

1. I have been designated by the Authorized User or Principal Investigator identified on the Green Mountain Care Board (GMCB) Data Use Agreement (DUA) #_____ as an Individual User who will use or have access to the information disclosed by GMCB under the DUA.

2. [X] I agree that I have read the DUA and agree to adhere to the provisions set forth in the DUA addressing the protection of confidential, restricted, personally identifiable and personal health information as required under Vermont law and regulations and by the federal Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) as the absolute baseline for data and information protection.

3. [X] I have read the DUA and agree to adhere to the requirements addressing the actions I will take in the event that there is a suspected or actual breach that could result in the unauthorized disclosure of confidential, restricted, personally identifiable and personal health information.

4. [X] I have read the DUA and agree to adhere to limiting the use and disclosure of the data and information provided by GMCB under this DUA to the uses and disclosures approved by GMCB and if applicable, as approved by the Department of Vermont Health Access (DVHA) for Medicaid data and by the Centers for Medicare & Medicaid Services (CMS) for Medicare data.

5. [X] I have read the DUA understand that I may be subject to civil, criminal and monetary penalties for violations use and disclosure guidelines as stipulated in the DUA authorized by GMCB and that GMCB and/or DVHA and/or CMS may prosecute to the fullest extent of applicable state and federal laws.

6. [X] I have read the DUA and agree to abide by all the provisions included in the DUA issued by GMCB including those provisions stipulated in the DUA between GMCB and CMS and those stipulated in the Memorandum of Understanding between GMCB and DVHA.

State of Vermont
Green Mountain Care Board
89 Main Street, Montpelier, VT 05620-3601

GMCB Limited Use Healthcare Research Data Sets: Individual User Affidavit

7. [X] I understand that to the extent any of the above terms of this affidavit conflict with the DUA that the terms of the DUA take precedent and that this Affidavit in no way abrogates or changes the DUA.

8 . I affirm under penalty of perjury that all of my statements above are true and correct.

November 15, 2017
Date

Susan E.V. Richardson
Individual User Signature

Susan E.V. Richardson
Name (Printed)

Research Specialist
Title

Vermont Child Health Improvement Program/University of Vermont
Organization/Employer

802-656-9193
Phone Number

susan.richardson@med.uvm.edu
Email Address

AUTHORIZED USER/PRINCIPAL INVESTIGATOR ONLY:

As the Authorized User and/or the Principal Investigator as defined in the GMCB DUA #_____ and as signatory on the Data Use Agreement, I have approved the access to and usage of the data for this above-identified Individual User as approved by GMCB and, if applicable.

Authorized User and/or Principal Investigator Signature

Charles MacLean
Name (Printed)

UVM College of Medicine
Organization/Employer

11.28.17
Date

1-3. Project Questions

Answer the following questions about your research project.

Yes ☒ No☐	Is the project directed by the State of Vermont?
Yes ☒ No☐	Is this project partially or wholly funded by the State of Vermont?
Yes ☐ No☒	Will the project products be used to directly generate revenues and income?
Yes ☒ No☐	Is the project useful for determining the capacity and distribution of existing health care resources?
Yes ☒ No☐	Is the project useful for identifying health care needs and informing health care policy?
Yes ☒ No☐	Is the project useful for evaluating the effectiveness of intervention programs on improving patient outcomes?
Yes ☒ No☐	Is the project useful for comparing costs between various treatment settings and approaches?
Yes ☒ No☐	Is this project useful for providing information to consumers and purchasers of health care?
Yes ☒ No☐	Is this project useful for improving the quality and affordability of patient health care and health care coverage?
Yes ☐ No☒	Does this project directly support public health activities?
Yes ☒ No☐	Does this project support educational purposes such as exploring the claims data for quality, potential uses, health services research training, or integration with other data sets?
Yes ☐ No☒	Does this project propose to link VHCURES data with any other individual record-level data sets? *If yes, describe the data sets and proposed methodology for linking in Section 1-5-4.*
Yes ☐ No☒	Does this project anticipate re-disclosure of the data set, custom extracts or analytical files generated from the data set to any identifiable external agents under contracts, grants, and agreements for research purposes that have been specified? *If yes, complete and file Attachment 3 and Attachment 4: Project Review Form.*

1-4. Requested Data

Indicate the data files requested in this application.

File Type	Commercial Insurers	Medicaid[1]	Medicare[2]	Data Years or Date Range[3]
Medical Eligibility-VT Residents	☒	☒	☒	2007-present

Medical Claims-VT Residents	☒	☒	☒	2007-present
Medical Eligibility- 5% National Sample	Not applicable	Not applicable	☒	2007-present
Medical Claims- 5% National Sample	Not applicable	Not applicable	☒	2007-present
Pharmacy Eligibility	☒	☒	Not applicable	2007-present
Pharmacy Claims	☒	☒	Not applicable	2007-present
Medicare Part D Event- VT Residents	Not applicable	Not applicable	☒	2007-present
Medicare Part D Event- 5% National Sample	Not applicable	Not applicable	☐	
Medicare MEDPAR	Not applicable	Not applicable	☐	

[1] *The Department of Vermont Health Access (DVHA) must approve uses and disclosure of Medicaid data.*

[2] *Medicare data may only be used for research directed and partially funded by the state of Vermont.*

[3] *VHCURES data are available on a consolidated CY quarterly or annual basis on paid claims date basis starting with CY 2007.*

1-5. Project Overview

1-5-1. Summarize the purpose and objectives of the proposed research. Describe how the research will contribute to generalizable knowledge applicable to the Vermont population, health, and health care and to the State of Vermont as applicable to the development, implementation, and evaluation of programs administered by Vermont state agencies.

Medical claims analysis is a method increasingly used by health care researchers to better understand health care utilization, treatment choices, and medical expenditures. The purpose of the repository is to create yearly datasets of Vermont patients from Vermont's all-payer claims dataset, the Vermont Healthcare Claims Uniform Reporting and Evaluation System (VHCURES) to be used by researchers at the University of Vermont.

The University of Vermont (UVM) has a data use agreement (DUA) with the Green Mountain Care Board (GMCB) to obtain data from VHCURES. The GMCB is responsible for Vermont's all-payer claims datasets, which include medical and pharmacy claims data, as well as insurance eligibility data for a large proportion of Vermonters. These data allow for population-based analyses of the health care system, and provide a comprehensive, longitudinal look at the changing healthcare landscape in Vermont. The agreement between UVM and the GMCB helps to fulfill the mission of the GMCB to support health services research by supplying datasets to researchers who have the competency and expertise to conduct proposed studies that will ultimately answer important healthcare questions about costs and utilization.